VS_3 - Visionsense Stereoscopic High Definition (3DHD) Vision System

User's Guide

CE
0086

July 2015
Revision 3.10 (EU)

Table of Contents

Chapter One

Introduction

- Caution: Federal Law restricts this device to sale by or on the order of a licensed physician or healthcare provider.

Visionsense Ltd. develops, manufactures and markets advanced stereoscopic visualization systems for the minimally invasive surgery (MIS). Visionsense's revolutionary vision system, the **VS_3**, is the world's most advanced stereoscopic endoscope to offer depth perception with high-resolution through small endoscope diameters.

Indications for Use

The **VS_3** system is intended for viewing internal surgical sites during invasive surgery.

The Visionsense **VS_3** Stereoscopic Vision System provides:

- Endoscope functionality with full stereoscopic capability
- Full depth vision with improved resolution
- Enhanced perception of tissue size and position
- Advanced human engineering
- Recordings of movies and snapshots in stereo and mono

Intended Audience

This manual is intended for physicians/surgeons and support staff using the **VS_3**. The manual covers procedures for preparing the system for use, using the system during procedures/surgery, as well as troubleshooting.

Organization of this Manual

This guide assumes that the authorized personnel have already prepared the **VS_3** system for use.

Chapter 2, "Overview", describes the **VS_3** system.

Chapter 3, "Preparing the **VS_3** System for Use", describes the steps you must take after installation to prepare the **VS_3** for use in the clinic or operating room.

Chapter 4, "Using the **VS_3** System", describes procedures performed during and after procedural/surgical use of the system.

Chapter 5 "Appendix: Parts and Modules", provides details on the **VS_3** system's hardware.

Chapter 6, "Troubleshooting the **VS_3** System", describes some minor problems that can be resolved by authorized clinic/hospital personnel.

Conventions Used in this Manual

The following typographic conventions are used in this manual:

Symbol	Text	Meaning
⚠	**Warning**	Indicates that the personal safety of the patient or physician may be involved. Disregarding a warning could result in injury to the patient or physician.
⚠	**Caution**	Indicates that the particular procedures or precautions must be followed to avoid possible damage to the product.
ⓘ	**Note**	Indicates information that may be helpful in the operation of the product.

ⓘ The terms endoscope, laparoscope and camera are used interchangeably throughout the manual, all referring to the **VS_{II}** and **VS_3** endoscopes.

Safety Instructions

Read this manual and carefully follow its instructions. The words **Warning** and **Caution** indicate special information that must be carefully reviewed to ensure the safe and effective operation of this product. Note that these words are accompanied by graphic symbols as indicated in the above section, Conventions Used in this Manual.

⚠

Warnings

Adhere to the following safety rules:

- Familiarize yourself with how the unit operates and is controlled, before using the unit on the patient.
- Only qualified personnel should operate the unit.

Warnings

- The unit is indicated for viewing internal surgical sites during general surgical procedures, for use in visualization of ventricles and structures within the brain during neurological surgical procedures, as well as viewing internal surgical sites during anterior and posterior spinal procedures, such as nucleotomy, discectomy, and foraminotomy, and to visualize the nasal cavity, nasal pharynx, upper airway, vocal cords, external ear canal and tympanic membrane during diagnostic and therapeutic procedures. Use of the unit in fields other than those indicated is not allowed for safety reasons.

- Unauthorized modifications to the unit are not allowed for safety reasons.

- Before using the unit, it is the user's responsibility to make sure that the unit is safe and operates properly.

- To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth

- The device cannot be used through instrumentation or an opening smaller than the outer diameter of the endoscope.

- When using the endoscope (through the same orifice) with other endoscopic equipment and/or endoscopically-used accessories, such as high frequency surgical equipment, laser equipment, or other medical electrical equipment, the combination should be comply with IEC 601-2-18 standard.

- During treatment with the unit, the patient must be treated with the usual medical care. This includes regular observation, checking on the progress of treatment, monitoring treatment conditions, etc.

- Avoid looking directly into a working endoscope (camera) tip for avoiding temporarily dazzle. If this happens, simply shift endoscope tip aside or alternatively unplug endoscope immediately.

- The Visionsense **VS_3** stereoscopic endoscopy system should ONLY be used by personnel with endoscopy experience in the surgical operating theater.

- The Visionsense **VS_3** stereoscopic endoscopy system should ONLY be used by personnel who have been formally trained on the operation of the system. Do not use the system without proper training.

- Do not use the endoscope to touch, push, perforate, or mechanically stress the tissue in any way. This is improper use as the device is not designed for this type of functionality. The endoscope should only be used for visualization and the tip should be kept away from tissue to enable a viewable image.

- Do not mechanically modify the device in any way (e.g.: do not try to polish the endoscope shaft or window). This will likely render the device unusable and may lead to an unsafe condition.

- If the device has been improperly used (e.g.: setting changes have been incorrectly made) , the most likely outcome will be either a very poor image (blurry and noisy) or no image at all. If you see these effects, discontinue using the device and use an alternate endoscopy system to complete the surgical procedure until a trained technical person returns the device to a proper state.

Warnings

- This medical device complies with EN60601-1-2 safety standard for electromagnetic compatibility, requirements and test. However, if this equipment is operated in the presence of high levels of electromagnetic interference (EMI) or highly sensitive equipment, interference may be encountered and the user should take whatever steps are necessary to eliminate or reduce the source of the interference. Diminished performance may lengthen operating time for anesthetized patient.

- If the glass window on the tip of the endoscope becomes coated with blood or bodily tissue, visualization will be disrupted. If this occurs, withdraw and wipe the endoscope tip; or, if the clinical situation permits, irrigate the tip with sterile water to remove the coating.

The device described in this manual has been designed and tested in accordance with Visionsense safety standards as well as European and international standards.

This guarantees a high degree of instrument safety. The system described in this user manual has been designed in compliance with the requirements of: EN, IEC, UL and CSA. In accordance with Directive 93/42/EEC & MDD 2007/47 for medical devices, the complete quality management system according to ISO 13485 of Visionsense, has been certified by notified body BSI (British Standards Institution), number 0086.

Equipment Compliance

The **VS_3** has been tested and found to comply with the following standards:

Standards No.	Standards Organization	Standards Title
60601-1-2	IEC	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - collateral standard: electromagnetic compatibility - requirements and tests (Edition 3).
60601-1	IEC	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
60601-1-4	IEC	Medical electrical equipment - Part 1: General requirements for safety, Collateral standard: Programmable electrical medical systems.

Equipment Classification:

According to the type of protection against electric shock: Class I equipment.

According to the degree of protection against electrical shock: Type BF Applied Part.

According to the mode of operation: Continuous operation.

Customer Support

In the event of any technical difficulties with your Visionsense equipment, contact your Visionsense representative. For your convenience, the contact information is as follows:

Customer Support:

Tel: +1-866-632-0907

e-mail: service@visionsense.com

Israeli Office

Visionsense Ltd.
20 Hamagshimim Street
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Fax: +972-3-924-4335

USA Office

Visionsense Corp.
248 Geiger Rd, Suite 201
Philadelphia, PA 19115
USA
Tel: 732-895-7710
Fax: 732- 640-5639

MDD - Authorized Representative in Europe

MEDES LIMITED
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Radlett, Herts, WD7 7AR
ENGLAND
Tel: +423-663-169205
Tel/Fax: +44-192-385-9810

Chapter Two

Overview

VS_3 - Visionsense Stereoscopic High Definition (3DHD) Vision System

Standard monocular endoscopes and video monitors flatten the view of the patient's anatomy in two dimensions. This lack of depth perception can significantly reduce the physician's/surgeon's perception of size and accurate location of the treated tissues, and thus potentially reduce the ability to diagnose and operate.

The **VS_3** – Visionsense Stereoscopic High Definition (3DHD) Vision System remedies this constraint of traditional endoscopic systems by providing the physician with natural stereoscopy, the two-eyed ability to judge depth, volume, or distance accurately. 'Stereo vision' is obtained when the eyes simultaneously pick up two slightly different images of the same object (right and left). **VS_3**'s technology provides physicians/surgeons with such stereo vision, enabling depth perception and so enhancing diagnostic and surgical judgment capabilities in the course of the surgical procedure. The image is picked up using a miniature proprietary sensor (a few mm.in size) and enhanced by an external, software-driven, digital video image processor.

In addition to traditional endoscopic procedures, the **VS_3** also permits recording surgical procedures, storing them on removable storage devices, and playing the procedures back.

System Architecture

The **VS$_3$** Endoscopic system consists of the following modules:

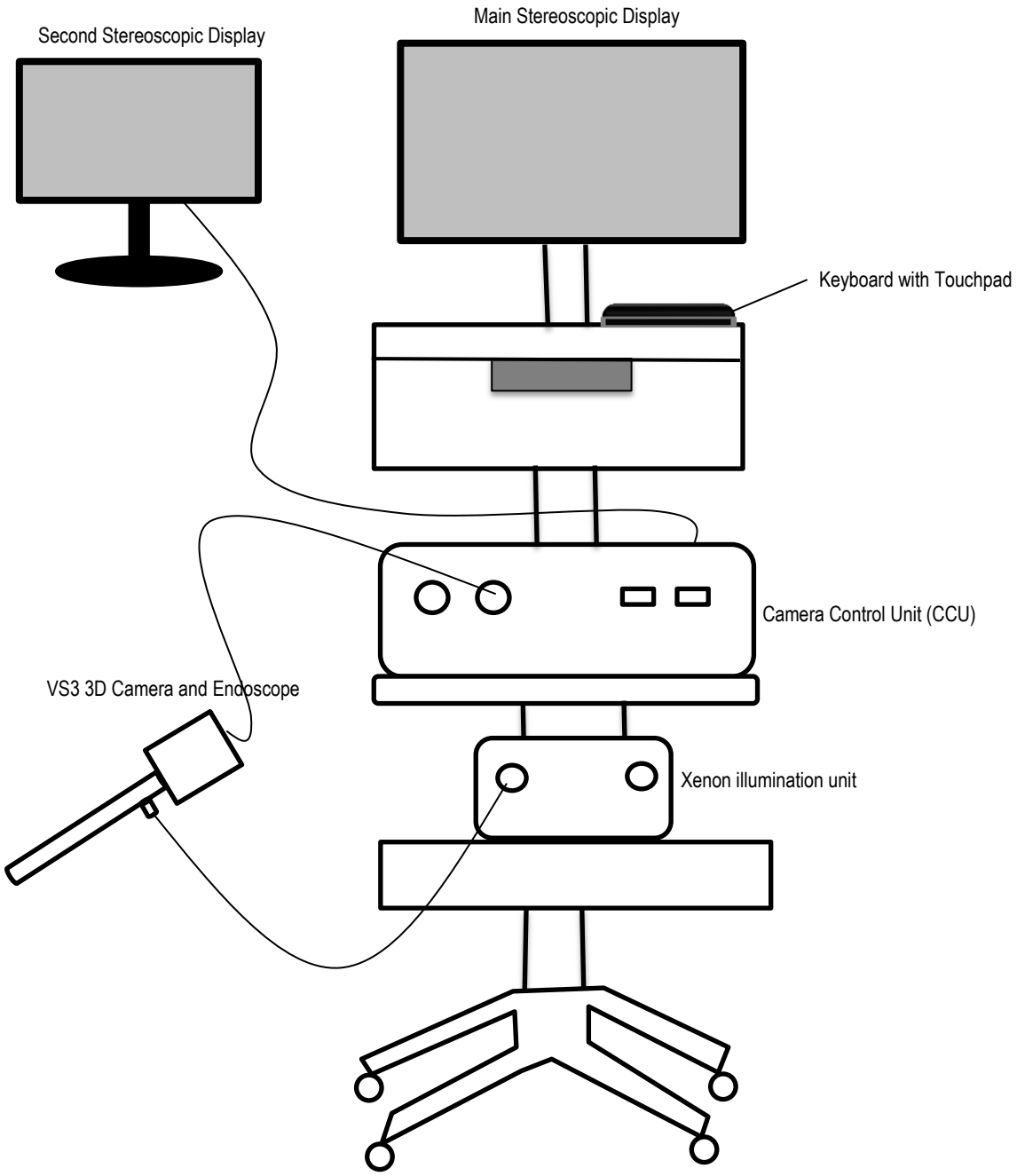


Figure 1: VS$_3$ System Architecture

The VS_3 Endoscopic Module (Applied Parts)

The **VS_3** Endoscopic Module includes the following applied parts:

- High Definition 3D Endoscope
- High Definition 3D Camera with 3 control buttons and a focus adjustment knob
- Coupler for 2D Endoscopes (namely: "2D Coupler") enables working with standard 3rd party 2D endoscopes. (optional)
- VS_3 Irrigation Cannula (optional)

To begin procedures, the endoscope must be connected to the camera by attaching the back of the endoscope to the camera's coupler while pressing the spring. Once the back of the endoscope is in the camera's coupler, the spring should be released to lock the scope and the camera together. The fiber optic Light Guide should be connected to the scope via a standard endoscope Light Guide connector with a screw terminal. The focus knob can be used during the surgical procedure to adjust the focus of the module based on distance from the objects in the surgical field.

To uncouple the endoscope from the camera, depress the spring and detach the endoscope from the camera by pulling it straight out of the coupler. The Light Guide should be detached from the endoscope by unscrewing the connector.

Warning

- Do not hold the camera in any way that will apply pressure on the spring during use as this may disengage the endoscope.

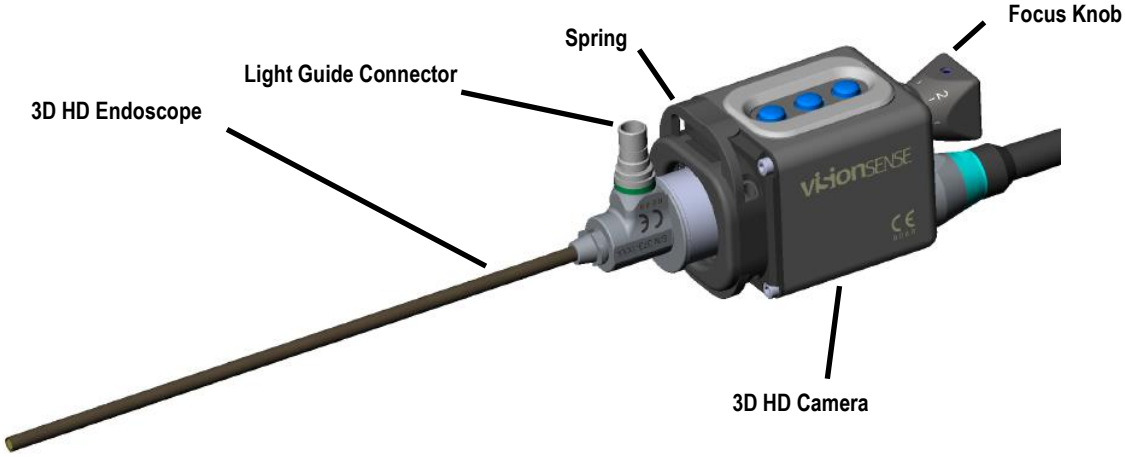
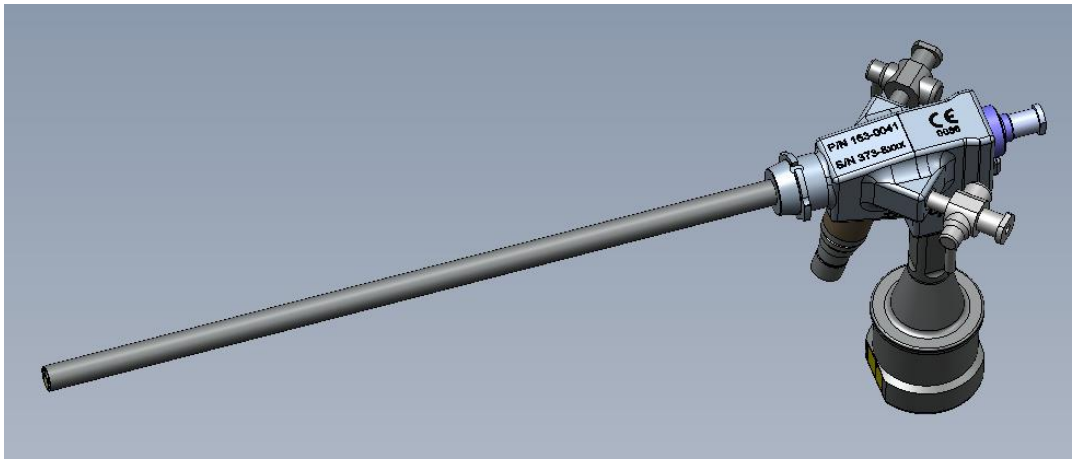


Figure 2: VS_3 Endoscopic module including Endoscope and Camera

The Endoscopic Third Ventriculostomy (ETV) 3D endoscope

The Endoscopic Third Ventriculostomy (ETV) 3D endoscope with working channels is supported in the **VS_3** system in the same way as a traditional endoscope. To use the ETV endoscope, connect the scope's eyepiece to the Visionsense 3D camera.



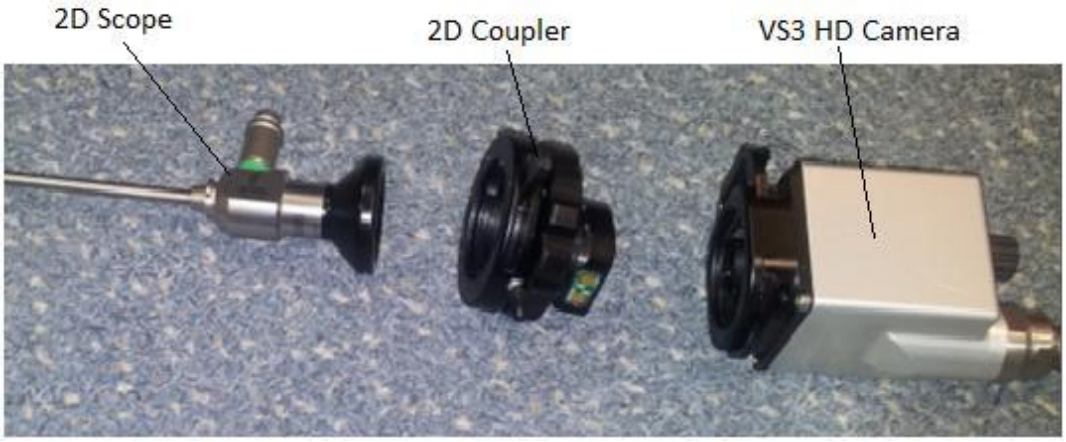
The ETV endoscope has a 6mm diameter shaft which includes the following:

- 3D visualization channel
- Single straight 2.2mm diameter working channel which can be used to pass rigid instruments

Two curved 1.4mm diameter side channels which can be used for irrigation/suction or flexible instruments

The VS_3 coupler for 2D Endoscopes

The 2D Coupler allows the **VS_3** HD Camera to be used with a standard third party's 2D endoscope (not provided by Visionsense). When used with a 2D Coupler the **VS_3** System produces a 2D image. To use the 2D Coupler, attach the Coupler to the **VS_3** HD Camera and then attach a standard 2D endoscope (not provided by Visionsense) to the 2D Coupler as per the pictures below.



Cannula (optional)

You can use a cannula along with the endoscope to keep the endoscope lens clear of debris, thereby maintaining maximum vision during a procedure.

To use the cannula, follow the steps below:

1. Slide the cannula over the endoscope and secure it by rotating the post in a clockwise direction.
2. Attach tubing from an irrigation pump or manual irrigation syringe to the Luer connector on the cannula.
3. When irrigation is required, activate the irrigation pump or push the plunger on the syringe. Water should pass through the cannula into the surgical field.

Chapter Three

Preparing the VS3 for Use

This chapter assumes that your Visionsense service representative has already assembled the system.

This chapter describes how you prepare the equipment for use in the clinical and/or operating room during an endoscopic procedure. It describes what you need to do after the **VS_3** System has been assembled and connected to the outlet.

The following steps describe what needs to be done to prepare the **VS_3** for use:

- Clean and disinfect or sterilize the Endoscope using the appropriate process, i.e. STERRAD or Autoclave (valid for marked Autoclave approved endoscopes).
- Deliver the unit to the clinic/operating room, in accordance with institutional regulations for handling disinfected/sterilized equipment.
- Position the **VS_3** System in the clinic/OR Environment.
- Make sure that the stereoscopic glasses are present.
- ***(OPTIONAL)*** Connect the mouse to one of the USB ports in the back of the console.

  (OPTIONAL) Connect the second stereo or monocular monitor to the **VS_3** console.

The following reprocessing instructions include cleaning and sterilization instructions for **VS_3** Camera, Cannula, Light Guide and 2D Coupler.

For the reprocessing guide for the optional **VS_{II}** Endoscope and cannula, see Appendix A.

Device Reprocessing

Reprocessing begins at point of use. Immediately following use of the device, ensure that the reusable device remains segregated from waste. Decontaminate the reusable device by wiping the device clean of all visible soil and keeping the wiped device contained while it is being transported to the dedicated cleaning work area at your facility. This initial wiping is intended to render the device safe for handling by health care workers and to make the device suitable for the subsequent thorough cleaning and sterilization steps. The device at this point is only safe for handling by the health care worker and is not suitable to be used on patients.

Once the device is at the designated cleaning work area, thoroughly clean the device in accordance with the cleaning instructions in the following sections. Use only the compatible cleaning detergents specified on the following pages of this manual to thoroughly clean the device, then rinse and dry the devices as described above to remove any unsafe residues.

The thoroughly cleaned device should then be terminally sterilized in accordance with the directions in this manual following the cleaning directions. Once the device has been

thoroughly cleaned AND sterilized, it may be returned to service in accordance with your hospital's standard procedures.

Cleaning and Sterilizing the VS_3 Endoscope, Cannula and Light Guide

The **VS_3** Endoscope, Cannula and Light Guide must be cleaned and sterilized before being used in a surgical procedure. The following sections describe the materials and procedures required for the cleaning and sterilization processes:

- Materials Required for Cleaning and Sterilization
- Cleaning the Endoscope, Cannula and Light Guide
- Sterilizing and Handling the Endoscope, Cannula and Light Guide

Materials Required for Cleaning and Disinfection or Sterilization

The authorized clinic/hospital personnel will need the following materials to carry out the processes of cleaning and sterilizing the **VS_3** endoscopes:

- Cleaning agents:
  - Enzymatic Detergent[1]
  - Non-Enzymatic Detergent[2]
  - Any cleaning solution that is approved by your institution's protocol for endoscopic equipment
- Tap water
- Sterile water
- Large water basin (approximately 40cm X 40cm X 20cm)
- Scrub brush (such as the "3M brush team")
- Sterile gauze pads
- Sterile, no powder gloves
- Protective attire according to institutional protocol
- Endoscope and protective cap
- Sterilization box

[1] ENDOZIME®, RUHOF CORP. Enzymatic Detergent was validated for cleaning efficacy

[2] RENU-KLENZ®, STERIS CORP. Non-Enzymatic Detergent was validated for cleaning efficacy

Preparing the VS_3 Endoscope 30° for cleaning and sterilization

In order to prepare the **VS_3** Endoscope 30° for cleaning, the Eyepiece must be detached from the main Endoscope body. These two parts are attached by a magnet, and need to be pulled away in order to separate them.

To detach the eyepiece from the main Endoscope body, do the following:

1. Hold the Endoscope firmly by its main body, near the light post. ***Do not hold the Endoscope by the shaft!!!***
2. With your other hand, hold the eyepiece firmly.
3. Rotate the eyepiece so that the red dot is aligned with the light post.
4. Gently detach the eyepiece from the scope body as shown in the following images:

Figure 3: Gently detach -- do not pull

Figure 4: Complete the detachment

Figure 5: Detached eyepiece and main body of VS3 Endoscope 30°

Preparing the VS_3 Endoscopic 3rd Ventriculostomy Endoscope (ETV) for cleaning and sterilization

In order to prepare the **VS_3** ETV Scope for cleaning, the irrigation valves must be removed from the main body before performing cleaning and sterilization cycles

To remove the valves from the main Endoscope body, do the following:

1. Hold the Endoscope firmly by its main body, near the light post. ***Do not hold the Endoscope by the shaft!!!***
2. Remove the valve cap by unscrewing it counter clockwise.
3. Then, remove the valve handle by pulling it outwards.
4. Remove the valves on both irrigation channels.

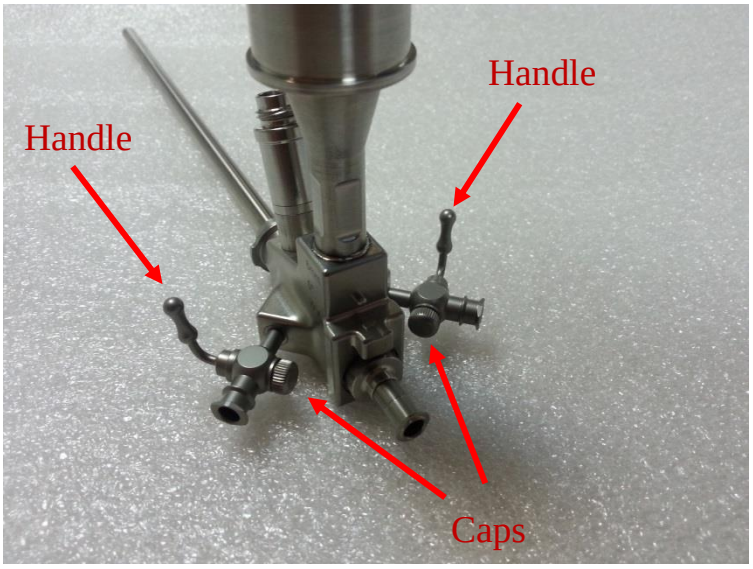


Figure 6: Irrigation valves - caps and handles

Figure 7: Disassembled caps and handles

When the cleaning and sterilization is complete, assemble the caps and handles as follows:

1. Hold the Endoscope firmly by its main body, near the light post.
2. Insert the handle into the valve and make sure the stop pin is in place:

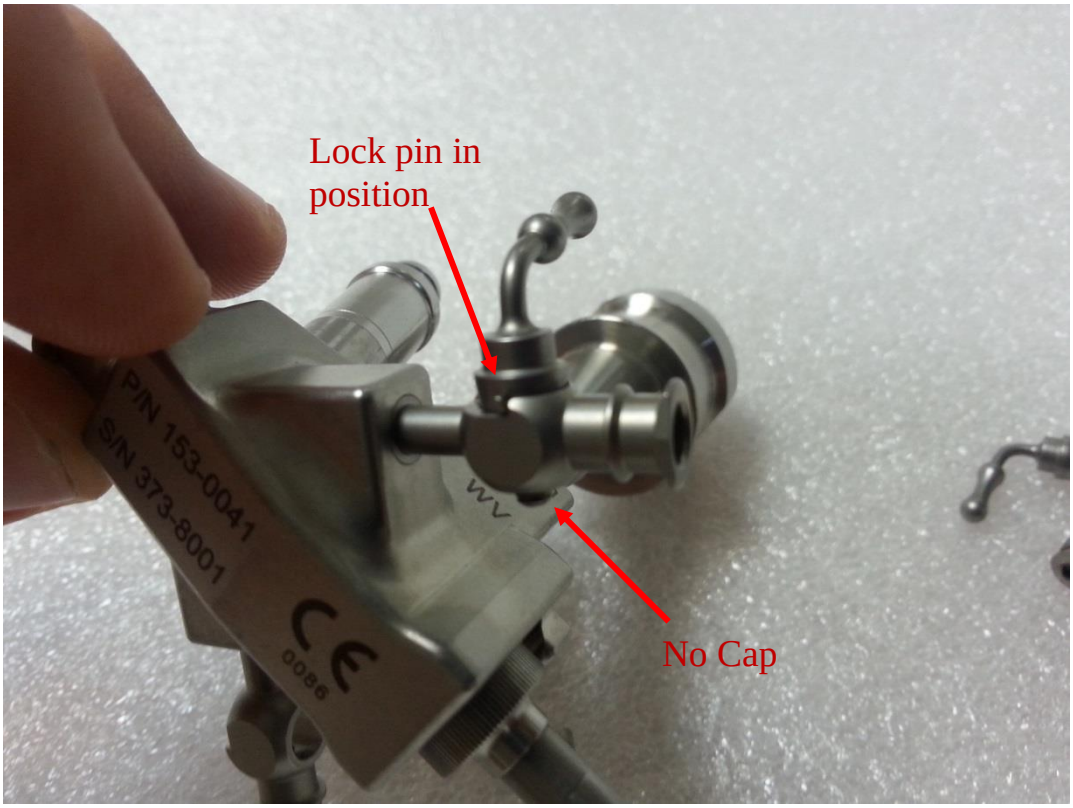


Figure 8: Handle insertion into the valve

3. Next, screw the cap back in place on the opposite side of the handle.
4. Do the same for both irrigation valves.

Cleaning the VS_3 Endoscope, Cannula and Light Guide

Both new endoscopes and those previously used in a procedure must be cleaned before disinfection or sterilization. When the physician/surgeon has finished using an endoscope, it must be promptly prepared for cleaning by the authorized personnel.

Manual Cleaning of VS3 Endoscope, Cannula and Light Guide

To thoroughly clean the endoscope, cannula and Light Guide:

1. **Wipe excess soil from the device with disposable paper towels.**
2. **Soak in enzymatic detergent:**
   - Prepare an enzymatic detergent solution with lukewarm tap water according to manufacturer's recommendations.
   - Wipe the entire surface of the device using a soft clean cloth dipped in the detergent solution.
   - Immerse the device in the detergent solution, ensuring the solution reaches all outer surfaces of the device. If applicable, use a syringe to inject any inside lumens (cannula, luer lock, stopcock) of the device with 50ml of the detergent to ensure all parts of the device are reached.
   - Soak the device in the solution for a minimum of 15 minutes.
3. **Brush**
   - Thoroughly brush the exterior of the device with a soft-bristled brush. Do not use an abrasive sponge under any circumstances.
   - Brush any lumens a minimum of 5 times from each end, using an appropriate bottle brush.
   - Brush any movable parts in all extreme positions.
   - When cleaning the Cannula, use appropriate brushes to clean the lumen of the Cannula as well.
4. **Rinse**
   - Remove the device from the detergent solution and rinse it with water at ambient temperature, for at least one minute, until all visible detergent is removed. Flush any lumens or mated surfaces a minimum of 5 times.
   - Rinse the device for an additional 30 seconds.
   - Drain any excess water from the device by holding it at an incline.
5. **Soak in Non-Enzymatic Detergent**

- Prepare a non-enzymatic solution in lukewarm tap water according to manufacturer's recommendations.
- Fully immerse the device and use a syringe to inject any lumens and mated surfaces with 50ml of the detergent.
- Soak the device in the solution for a minimum of 15 minutes.

6. Brush

- While submerged in solution, thoroughly brush the device. When cleaning the Cannula, use appropriate brushes to clean the lumen of the Cannula as well.
- Brush any lumens a minimum of 5 times from each end, using an appropriate bottle brush.
- Actuate the device, brushing around any movable parts in all extreme positions.

7. Rinse

- Remove the device from the detergent solution and rinse it with water at ambient temperature, for at least on minute, until all visible detergent is removed.
- Flush all lumens, crevices, and mated surfaces with a minimum of 50mL of water.
- After all detergent residues are removed rinse the device for an additional 30 seconds.
- Drain any excess water from the device by holding it at an incline.

8. **Dry**

- Dry the device using a clean cloth. Filtered pressurized air can be used to assist in drying.
- Leave in open air for ten minutes to ensure it is completely dry.

9. Inspect

- Visually inspect the device for remaining soil.
- If soil remains, repeat the manual cleaning procedure, focusing on those areas.
- After the cleaning has been completed, the endoscope can be stored or sterilized for immediate use.

Automated Cleaning of VS3 Endoscope, Cannula, and Light Guide (***not applicable for ETV Endoscopes!***)

Perform the following procedure for automated cleaning:

1. Rinse the Endoscope, Cannula, and Light Guide in warm tap water to remove any tissue debris and/or bloody residue.
2. Place the Endoscope, Cannula, and Light Guide in the sterilization tray. Make sure that the Endoscope is properly fixated in the sterilization tray. Place the distal part of the Endoscope (shaft) through the silicon fixation opening and the proximal thick part of the Endoscope between the silicon fixations. Ensure that the Light Guide is neatly placed in the sterilization tray and free of kinks. Keep the Light Guide ends in the middle of the sterilization tray (see figure below).
3. Position the cannula in the sterilization tray in a way that the automated washer will flush out the cannula and channel. If needed, adjust the washer's sprinkles as need to verify it flushes the cannula.
4. Each of the modules (Endoscope, Cannula, and Light Guide) may be placed in separate sterilization trays if needs to be cleaned by itself (see figures below).
5. Use the automated washer according to hospital protocol for using such a cleaner.[3]
6. After the cleaning has been completed, the Endoscope, Cannula, and/or Light Guide can be stored or disinfected/sterilized for immediate use.

Figure 9: Stored Endoscope, Cannula and/or Light Guide

[3] Visionsense has validated an automated washer cycle of 5 minutes at 50°-60°C (washing), and additional 5 minutes at 90°-95°C (Disinfection).

Figure 10: Endoscope and Cannula Sterilization tray

Figure 11: VS_3 Light Guide Sterilization tray

After the cleaning has been completed, the Endoscope, Cannula, and/or Light Guide can be stored or disinfected/sterilized for immediate use.

Terminally Sterilizing the VS_3 Endoscope, Cannula, and Light Guide

The **VS_3** endoscopic equipment is supplied non-sterile and must be terminally sterilized by authorized clinic/hospital personnel prior to use. In the current version of the **VS_3** system, authorized personnel can sterilize the **VS_3** Endoscope, Cannula, and Light Guide using low temperature sterilization processes, such as STERRAD® (STERRAD® 50/100S/200/NX/100NX Systems) or steam autoclave at 134°C for at least 3 minutes.

Cautions

Note the following precautions prior to sterilizing the **VS_3** Endoscope, Cannula and Light Guide:

- Follow manufacturer instructions for sterilization.
- Ultrasonic cleaning methods **are prohibited** when cleaning or sterilizing the **VS_3** Endoscope, Cannula and/or Light Guide.

- Do not sterilize the **VS_3** Endoscope, Cannula and Light Guide using gamma irradiation

- Do not use cleaning and/or sterilization processes that have not been validated.

Warning

- This device is used in the neurosurgical field where there is a high-infectivity risk of Creutzfeldt-Jakob disease (a.k.a. TSE, CJD) or similar prions in patients who are known or suspected to be infected. Dispose or destroy devices that have been used on patients suspected of having Creutzfeldt-Jakob disease or other prion diseases according to the WHO guidelines, unless sterilizing the devices with STERRAD 100NX Standard Cycle process which is currently thought to eradicate prions. This device is fabricated of materials which can withstand the reprocessing exposure conditions of STERRAD 100NX sterilization. To learn more about this disease you may wish to consult the WHO guidelines - World Health Organization's 1999 guidance document (Infection Control Guideline for Transmissible Spongiform Encephalopathies. Geneva, Switzerland).

- The qualified ASP STERRAD® Sterilization Systems are: STERRAD® 50, 100S, 200, NX Standard Cycle, and 100NX, Standard and DUO Cycles only (100NX Express Cycle is not qualified). Please refer to ASP/ STERRAD® System User's Guide for the appropriate cycle in each STERRAD® system for the instrument to be reprocessed. All instruments must be cleaned, rinsed, and thoroughly dried prior to placement in a STERRAD® sterilizer.

Cleaning and Sterilizing VS_3 Camera and Coupler for 2D Endoscopes

The **VS_3** Camera and 2D Coupler must be cleaned and sterilized before being used in a surgical procedure. The following sections describe the materials and procedures required for the cleaning and sterilization processes:

- Materials Required for Cleaning and Sterilization

- Cleaning the Camera and 2D Coupler

- Sterilizing and Handling the Camera and 2D Coupler

Materials Required for Cleaning and Disinfection or Sterilization

The authorized clinic/hospital personnel will need the following materials to carry out the processes of cleaning and sterilizing the **VS_3** Camera and 2D Coupler:

- Cleaning agents:
  - Enzymatic Detergent[1]
  - Non-Enzymatic Detergent[4]
  - Any cleaning solution that is approved by your institution's protocol for endoscopic equipment - **See the following cautions:**

Cautions

- **Cleaning agents must state Aluminum Suitability by the manufacturers**
- **Cleaning agents should be up to pH=10.0**

- Tap water
- Sterile water
- Large water basin (approximately 40cm X 40cm X 20cm)
- Scrub brush (such as the "3M brush team")
- Sterile gauze pads
- Sterile, no powder gloves
- Protective attire according to institutional protocol
- Endoscope and protective cap
- Sterilization box

Cleaning the VS_3 Camera and Coupler for 2D Endoscopes

Both new cameras and those previously used in a procedure must be cleaned before disinfection or sterilization. When the physician/surgeon has finished using a camera, it must be promptly prepared for cleaning by the authorized personnel.

MANDATORY - Prior to any cleaning or immersing, make sure to cover the male part of the medical connector attached to the camera's main cable with the protective cap and to properly tighten the cap.

Cautions

- Failure to cover the camera's connector will result in irreparable damage to the camera.
- Ultrasonic cleaning methods **are prohibited** when cleaning or sterilizing the camera or 2D Coupler. Cleaning must be done by hand only.

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[7]RENU-KLENZ®, STERIS CORP. Non-Enzymatic Detergent was validated for cleaning efficacy

Manual Cleaning of VS_3 Camera:

To thoroughly clean the VS3 Camera:

1. **Prepare**
   - Ensure the protective cap is screwed over the connector at the end of the cable, to protect from liquids. Roll the cable with a radius of at least 10 inches.
2. **Wipe**
   - Wipe excess soil from the device ("device": the full camera, including the cable & connector cap) with disposable paper towels.
3. **Soak in enzymatic detergent:**
   - Prepare an enzymatic detergent solution with lukewarm tap water according to manufacturer's recommendations.
   - Wipe the entire surface of the device using a soft clean cloth dipped in the detergent solution.
   - Immerse the device in the detergent solution, ensuring the solution reaches all outer surfaces of the device.
   - Soak the device in the solution for a minimum of 15 minutes.
4. **Brush**
   - Thoroughly brush the exterior of the device with a soft-bristled brush. Do not use an abrasive sponge under any circumstances.
5. **Rinse**
   - Remove the device from the detergent solution and rinse it with water at ambient temperature, for at least on minute, until all visible detergent is removed.
   - After all detergent residues are removed, rinse the device for an additional 30 seconds.
   - Drain any excess water from the device by holding it at an incline.
6. **Soak in Non-Enzymatic Detergent**
   - Prepare a non-enzymatic solution in lukewarm tap water according to manufacturer's recommendations.
   - Immerse the device in the detergent solution, making sure the solution reaches all inner and outer surfaces of the device.
   - Soak the device in the solution for a minimum of 15 minutes.
7. **Brush**
   - While submerged in solution, thoroughly brush the device, including in the inner area of the spring, with an appropriately sized brush.
8. **Rinse**

- Remove the device from the detergent solution and rinse it with water at ambient temperature, for at least one minute, until all visible detergent is removed.
- Flush all lumens, crevices, and mated surfaces with a minimum of 50mL of water.
- After all detergent residues are removed rinse the device for an additional 30 seconds.
- Drain any excess water from the device by holding it at an incline.

9. Dry

- Dry the device using a clean cloth. Filtered pressurized air can be used to assist in drying.
- Leave in open air for ten minutes to ensure it is completely dry.

10. Inspect

- Visually inspect the device for remaining soil.
- If soil remains, repeat the manual cleaning procedure, focusing on those areas.
- After the cleaning has been completed, the endoscope can be stored or sterilized for immediate use.

Manual Cleaning of VS_3 Coupler for 2D Endoscopes

VS_3 Coupler for 2D Endoscopes ("2D Couplers") is reusable and must be thoroughly cleaned after each use to remove contaminating substances prior to sterilization.

To thoroughly clean the 2D Coupler after each use:

1. Wipe

- Wipe excess soil from the device with disposable paper towels.

2. Soak in enzymatic detergent:

- Prepare an enzymatic detergent solution with lukewarm tap water according to manufacturer's recommendations.
- Wipe the entire surface of the device using a soft clean cloth dipped in the detergent solution.
- Immerse the device in the detergent solution, ensuring the solution reaches all outer surfaces of the device.
- Soak the device in the solution for a minimum of 15 minutes.

3. Brush

- Thoroughly brush the exterior of the device with a soft-bristled brush. Do not use an abrasive sponge under any circumstances.

4. Rinse

- Remove the device from the detergent solution and rinse it with water at ambient temperature, for at least on minute, until all visible detergent is removed.
- After all detergent residues are removed, rinse the device for an additional 30 seconds.
- Drain any excess water from the device by holding it at an incline.

5. Soak in Non-Enzymatic Detergent

- Prepare a non-enzymatic solution in lukewarm tap water according to manufacturer's recommendations.
- Remove the grommet temporarily.
- Immerse the device in the detergent solution, making sure the solution reaches all inner and outer surfaces of the device.
- Soak the device in the solution for a minimum of 15 minutes.

6. Brush

- While submerged in solution, thoroughly brush the device with an appropriately sized brush.

7. Rinse

- Remove the device from the detergent solution and rinse it with water at ambient temperature, for at least on minute, until all visible detergent is removed.
- Flush all lumens, crevices, and mated surfaces with a minimum of 50ml of water.
- After all detergent residues are removed rinse the device for an additional 30 seconds.
- Drain any excess water from the device by holding it at an incline.

8. Dry

- Dry the device, including the lumen, using a clean cloth. Filtered pressurized air can be used to assist in drying.
- Leave in open air for ten minutes to ensure it is completely dry.

9. Inspect

- Visually inspect the device for remaining soil.
- If soil remains, repeat the manual cleaning procedure, focusing on those areas.
- After the cleaning has been completed, the device can be stored or sterilized for immediate use.

Terminally Sterilizing the VS_3 Camera and 2D Coupler

The **VS_3** endoscopic equipment is supplied non-sterile and must be terminally sterilized by authorized clinic/hospital personnel prior to use. In the current version of the **VS_3** system, authorized personnel can sterilize the **VS_3** camera and 2D Coupler using low temperature sterilization processes, such as STERRAD® (STERRAD® 50/100S/200/NX/100NX Systems).

Cautions

Note the following precautions prior to sterilizing the VS_3 Camera:

- Follow manufacturer instructions for sterilization.
- Do not sterilize the **VS_3** Camera and 2D Coupler using gamma irradiation
- Do not perform autoclave sterilization for **VS_3** Camera and 2D Coupler. This can damage the devices irreversibly!
- Do not use cleaning and/or sterilization processes that have not been validated.

Warning

- Do not remove the protective cap of the **VS_3** Camera before cleaning – not even during the transition between cleaning and sterilizing. Removing the protective cap may result in a contaminated device. Only authorized personnel outside the sterile zone should remove the protective cap prior connecting the Camera's connector to the Camera Control Unit (CCU).
- For sterilization using the STERRAD method, the protective cap must be sealed for protection.
- The qualified ASP STERRAD® Sterilization Systems are: STERRAD® 50, 100S, 200, NX Standard Cycle, and 100NX, Standard and DUO Cycles only (100NX Express Cycle is not qualified). Please refer to ASP/ STERRAD® System User's Guide for the appropriate cycle in each STERRAD® system for the instrument to be reprocessed. All instruments must be cleaned, rinsed, and thoroughly dried prior to placement in a STERRAD® sterilizer.

Draping of VS_3 Camera and 2D Coupler in the OR

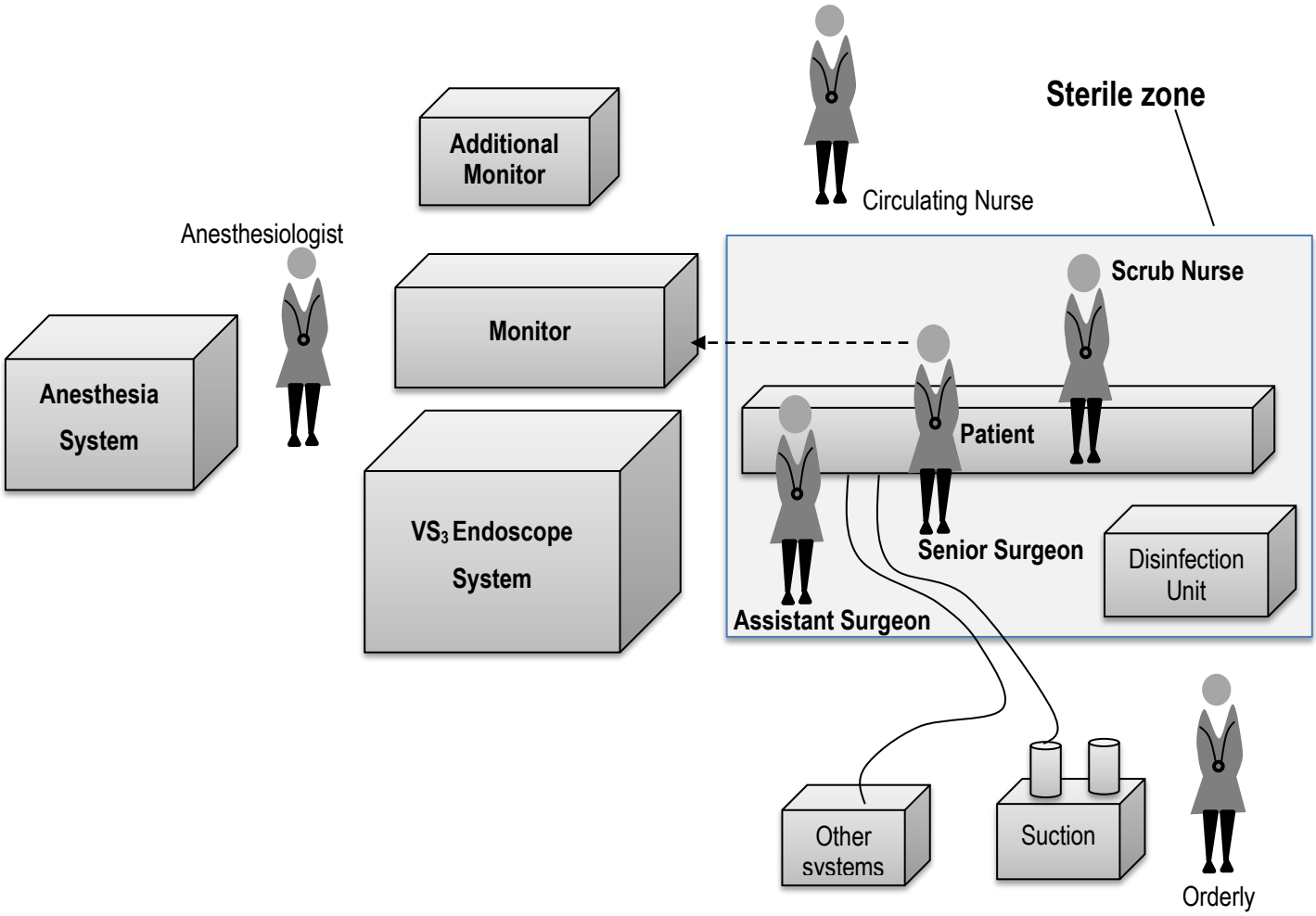
In case the hospital chooses not to sterilize the VS_3 Camera and 2D Coupler, the camera and 2D Coupler can be draped in the OR. There are multiple approved types of Video Camera Drapes available on the market. For applying the drape to the camera please refer to the recommended draping technique supplied by manufacturer of the used camera drape.

Handling the Sterilized Or Draped Devices

After the sterilization process has been completed, the clinic/hospital-authorized personnel must deliver the unit to the clinic/operating room, in accordance with the clinic/hospital regulations for handling sterilized equipment.

Positioning the System in the Clinic/OR Environment

The following schematic suggests the optimal positioning of the **VS$_3$** system in the OR:



How to position the system

Position the system as close as possible to the sterile zone, up to 6 feet (2 meters away).

Make sure to align the **VS$_3$**'s monitor to the physician's/surgeon's eye level. The field of vision is up to 10° above or below the center. The optimal position for viewing the image is facing the monitor straight ahead.

Managing the different devices within the sterile zone

The VS$_{II}$ and **VS$_3$** endoscopes and cameras are sterilized devices positioned in the sterile field. These are sterilized before each procedure. Surgeons wear 3D Glasses which are

placed on them by a non-sterile nurse (same procedure as protective glasses or loupes). These are passive 3D glasses that do not require any further adjustments once placed.

The end side of the sterile cable of the 3D camera is handed over to a non-sterile nurse to be plugged into the non-sterile system. The orderly or circulating nurse opens the cap so that the connector won't contaminate the sterile zone.

Temperature and Lighting

Room temperature – Per institutional protocol.

Ambient lighting - The recommended illumination of the room should be as minimal as possible. For best results, set one light source over the work table, and set an additional light source over the anesthesiologist's working area (if applicable).

Chapter Four

Using the VS3 System

Using Visionsense follows the normal cycle of a surgical procedure

Using the **VS_3** Endoscopes is straightforward and no different than using a standard endoscope. The VS_3 console features a Camera Control Unit (CCU) and uses an advanced stereoscopic monitor, which when viewed with polarizing glasses, provides full 3D depth perception on-screen. This innovative capability enhances the physician's/surgeon's ability to make real-time diagnostic and procedural/surgical decisions during the endoscopic procedure. In addition, the VS_3 Endoscope provides comprehensive recording and data management features.

Using the endoscope in this way involves just a few simple steps:

1. Connect up the system. (Optional) Connect a secondary stereo or monocular monitor.
2. Use the endoscope in the procedure.
3. Disconnect the endoscope and shut down the system.

Special Features

The **VS_3** system also provides the following special features:

- Select image preferences.
- Flip the image.
- Change the image size
- Record the procedure video
- Take snapshots of the procedure.
- Download the recorded data to a removable storage device.
- View the recordings of the procedure.

Some of these features may be used while the camera is connected, while other features may only be used while the camera is disconnected from the system. Generally, you can only view the recordings of the procedure while the camera is disconnected.

Starting and Running the Visionsense Stereoscopic Endoscope System

The following procedures provide instructions for using the **VS_3** Endoscope as a standard endoscopic system. These instructions assume that you have already followed the instructions in Chapter 3 for preparation and sterilization of the equipment.

Step 1: Connecting Up the VS3 System

Before you can use the **VS_3** Endoscope, you must connect the system modules to each other and to a power source. Follow the steps here to connect and verify that the system is ready for use.

To connect up the VS_3 System for an endoscopic procedure:

1. Connect the system to an external power source.
2. (Optional) If using a secondary monitor, see **to connect a secondary monitor** section on page 40.
3. Turn on the **VS_3** System by pressing the ON/OFF button. A green LED lights up to indicate the system is on.
4. Verify that the system is ready for operation. You should be able to see a background on the monitor with the words "No Camera Connected" on the bottom like this:

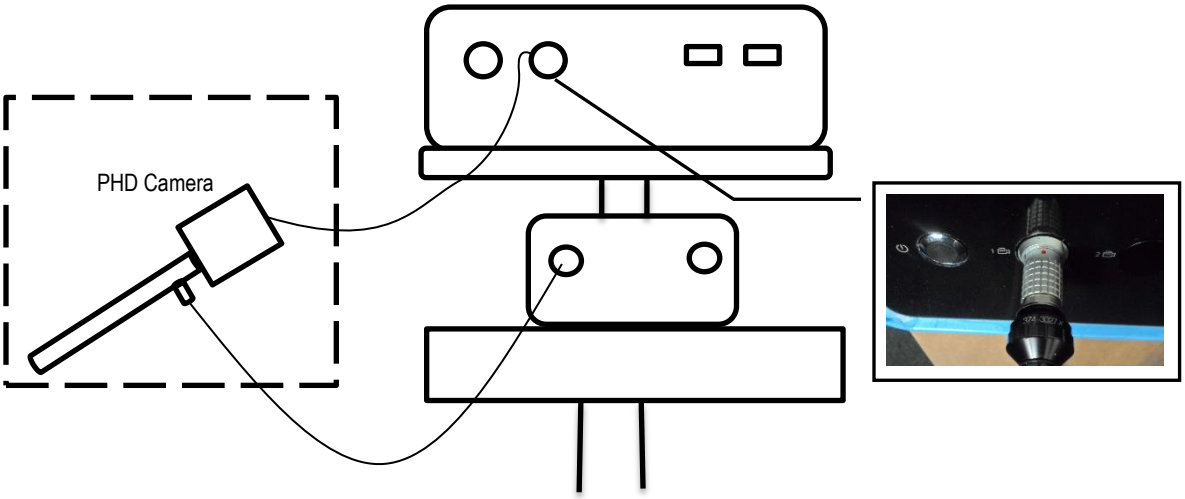
5. Remove the protective cap attached to the 3DHD Camera main cable connector (see figure below). This cap is a sealed protective cover designed to protect the connector while reprocessing.

Cautions

- Do not detach the protective cap from the unit.

- Do not pull on the cable connected to the camera.

6. Connect the 3DHD Camera cable to the camera port on the Camera Control Unit (CCU). Make sure to align the red dot on the camera connector with the red stripe on the system port. (The red dot should be facing up when connected to the CCU.):



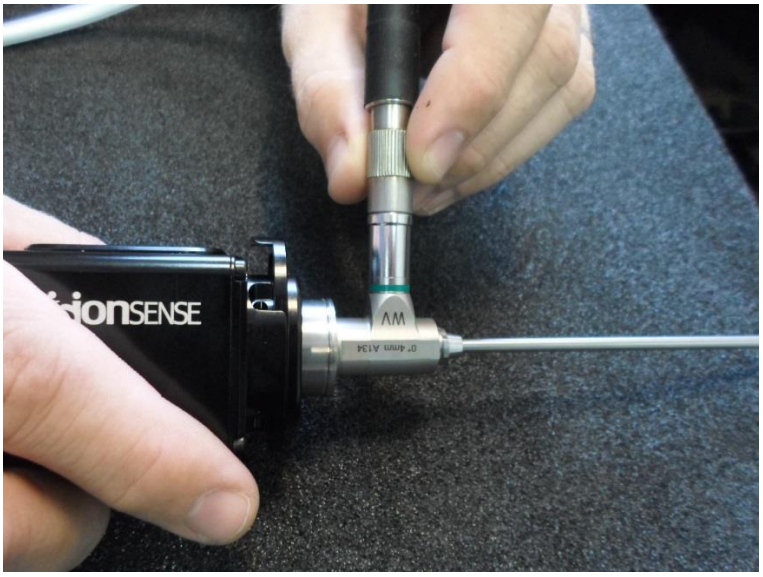
(For the optional VS_{II} Endoscope, connect in a similar manner to the port adjacent to the **VS_3** connection port on the CCU.)

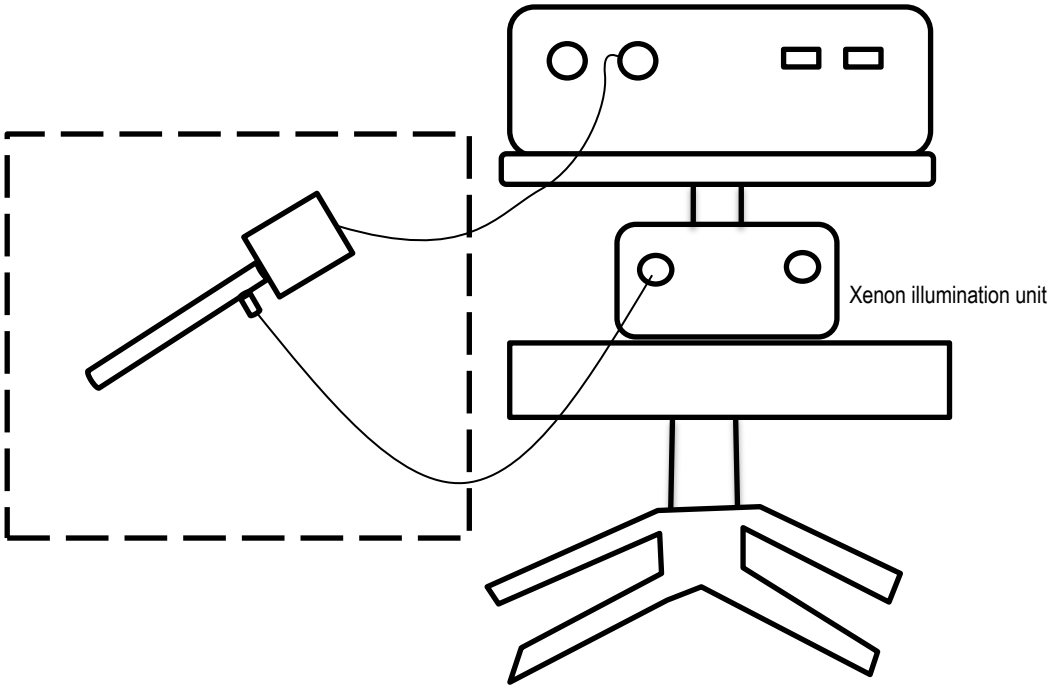
Warnings

- The connector to the system is non-sterile.
- Do not connect both VS_{II} and VS_3 cameras together. An error message will appear on the screen and live image will be blocked in such a case.
- Do not insert any other endoscope or illumination unit other than the one provided with the system.
- Do not perform procedures without the provided polarizing glasses.
- Do not operate with a camera that is not recognized by the system (an on-screen message alerts you to this).

7. Connect the VS_3 Endoscope to the 3DHD camera by pressing the attachment spring on the camera head and inserting the Endoscope to its position.

8. Connect the endoscope to the illumination port on the CCU (or alternatively to an external 3rd party illumination unit):





9. (optional) connect the irrigation Cannula to the Endoscope as follows:
   a. Slide the cannula over the endoscope and secure it by rotating the post in a clockwise direction.
   b. Attach tubing from an irrigation pump or manual irrigation syringe to the luer connector on the cannula.
   c. When irrigation is required, activate the irrigation pump or push the plunger on the syringe. Water should pass through the cannula into the surgical field.

To verify that the image is Stereoscopic (3D), perform the following test:

1. Look at the monitor at eye level with polarizing glasses.
2. Cover your right eye. You should see a small letter "L" in blue at the bottom left of the monitor.
3. Then cover your left eye and the letter "L" disappears.

To connect a secondary stereo monitor or a monocular monitor (optional):

Verify the system is shut down before performing the following steps.

1. Connect the secondary monitor cable connector to the secondary monitor DVI connector port on the back of the CCU:

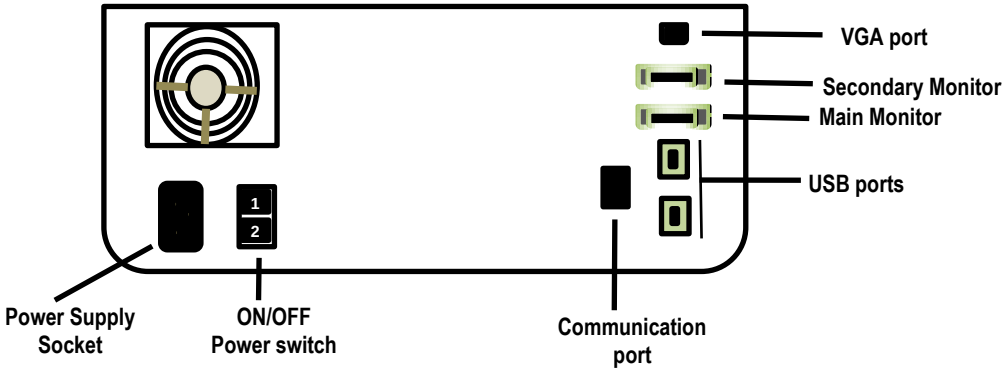


Figure 12: Back of CCU

2. Turn on the monitor.
3. Turn on the system.

Step 2: Using the VS_3 Endoscope System

To use the 3D Endoscope during a procedure:

1. Put on the polarizing glasses provided with the system (they will provide the depth perception).
2. Use the endoscope as you would operate any other endoscope.

Step 3: Shutting Down the System

After finishing the procedure, shut down the system as follows:

1. Press the ON/OFF button located on the front left side of the CCU.

   The following message appears:

Please press again to shut down the system.

2. Press the ON/OFF button again to shut down the system.
3. Disconnect the camera main cable from the system by pulling back the camera connector sleeve until fully retracted and then pulling the cable.
4. Close the camera connector's protective cover.
5. Promptly deliver the camera to your authorized personnel for cleaning, sterilization, and storage. The authorized personnel will sterilize the camera in compliance with institutional protocols.
6. Disconnect the system from the external power source.

Cautions

- Do not disconnect the system from the external power source without a proper shutdown.

Using VS_3's Special Features

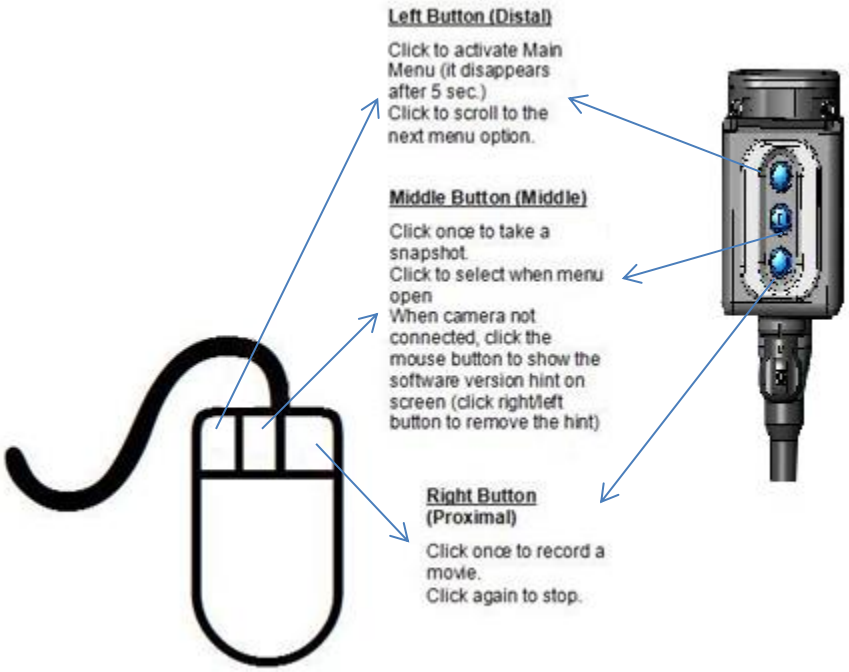
The **VS_3** system provides advanced features that permit customizing the stereoscopic image attributes, recording the procedure, moving recorded data to a removable storage device and viewing the recorded data. To perform these tasks, you use the control buttons and the **VS_3** menu options displayed on the monitor as shown below.

Note: Different menus are displayed depending on whether or not a camera is connected to the system.

Where **Control Buttons** are mentioned, they refer to either the touchpad\mouse buttons or the camera buttons which perform identical actions.

Using the Endoscope and Touchpad\Mouse Buttons

The **VS_3** system has control buttons accessible on the **VS_3** Camera in the sterile field to enable quick use during the procedure. Alternatively, you can use the touchpad on the keyboard to scroll to and select a menu item, and to operate the camera. You can optionally attach a mouse for the same purpose. The following figure shows the actions performed by the camera buttons and mouse buttons when a mouse is used:



Note: Using the Keyboard

When using the keyboard and touchpad the following keyboard keys correspond to the middle mouse button:

s: takes a snapshot

b: displays the software version

Recording the Procedure

The **VS$_3$** enables easy recording of an endoscopic procedure video.

Recordings can be transferred to a removable storage device (USB flash memory or an external hard drive). The recordings are available for viewing after a procedure, as either a stereo movie or a mono movie. Stereo movies may be viewed using the **VS$_3$** System or any movie player supporting stereo video. When using a 2D personal computer or laptop to play a movie, the image will be seen in mono.

A recording can be stopped/started at any time during the procedure.

To record a procedure:

- During the procedure, click the **Proximal Camera Button** or right mouse/touchpad button. At the top left corner of the monitor, an icon with a time indicator is displayed, indicating that the recording is taking place.

System's capacity is approx. 24H of recorded videos. New recordings will delete and replace the oldest recorded data.

Therefore, it is recommended to download the recorded data to a removable storage device key to prevent data loss. See Managing Recordings section on page 45.

To stop the recording:

- Click the **Proximal Button** or the right mouse/touchpad button again to stop recording (the icon will disappear from the screen). The recorded file is temporarily saved in the system.

See section entitled Managing Recordings on page 45 to learn how to save recorded data onto a removable storage device.

Caution

- Recordings cannot be viewed while a camera is connected to the system.

Taking a Snapshot of the Procedure

The **VS_3** System enables taking snapshots of surgical procedures. A snapshot is defined as making a temporary copy of one selected image (like a photograph). Like recordings, snapshots of procedures can be used in a variety of ways, including educational purposes and demonstrations at professional presentations and conferences.

To take a snapshot of a procedure:

- During the procedure, click the camera **Middle Control Button, press 's' on the keyboard, or click the mouse middle button**. A white frame will flash on the image, indicating that the snapshot has been taken.

See section entitled **Copying to a USB** on page 47 to learn how to save recorded data onto a removable storage device.

Menu options when no camera is connected to the system

When there is no camera connected to the system, the surgeon can view recordings of previous procedures. Options for **Maintenance** and **Service** of the system are also displayed, but available only to Visionsense personnel. The menu looks like this:

The options are as follows:

Back

Click on Back at any time to exit the Main Menu.

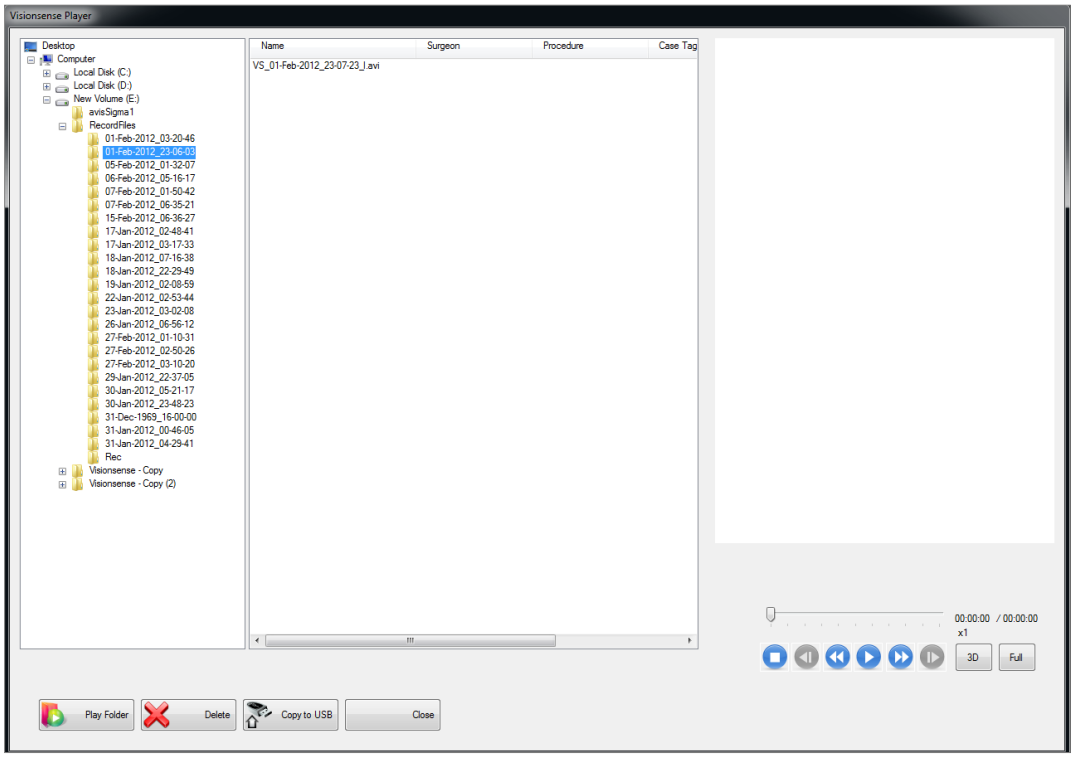
Please note: the menu will automatically close after 10 seconds of inactivity.

Managing Recordings

The **VS$_3$** System enables the surgeon to store as well as view recordings of previous procedures. The surgeon can control the playback of the recording, as well as perform management activities such as backing up the recording to a USB device.

The **VS$_3$** System allows you to store up to 24 hours of recordings. After using up 24 hours of content, the system will overwrite oldest recordings with new video. If this happens, the old recordings will not be accessible. For this reason, it is crucial to periodically download recordings to a removable storage device.

To access the Manage Recordings screen, from the **Main Menu**, choose **Manage Recordings** – the following screen is displayed:



Playing a recording

You can play films of previously recorded procedures.

To play a film:

1. In the File Browser (left pane), browse the folders and files until you locate the movie that you want to play.
2. Select the movie and click the Play button on the control panel (lower right pane) to play the film:

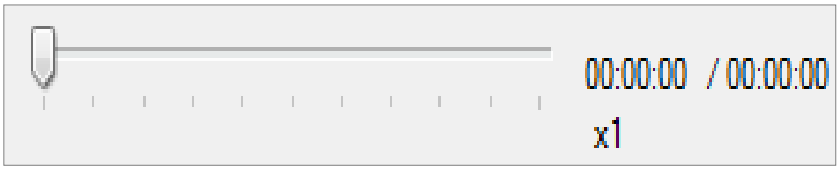
Using the Control Panel

Use the control panel to control the playback of the film as follows:

Button	Function	Keyboard Shortcut
	Play/Pause	'Space'
	Stops the movie and returns you to the beginning of the movie.	(None)
	Previous/Next Movie	'<' / '>'
	Decrease/Increase speed of playback. Each click increases/decreases in increments of 0.25, from 0.25x to 2.0x.	'+' / '-'
3D	Toggles between 2D and 3D view.	'2'
Full	Toggles between full screen and regular display.	'F'

Play Bar

The elapsed time of the movie is displayed near the Play bar as shown below. You can use the slider on the Play bar to jump to various parts in the movie:



Playing an Entire Folder

You can play an entire folder of movies by clicking the Play Folder button 

below the File Browser pane. After the first movie plays, the player consecutively plays each movie in the folder's list of files.

You can stop the playback at any time by clicking the Stop Playback button 

.

Close

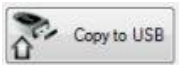
Click the Close button 

below the Browser pane to exit the Manage Recordings window and return to the Main menu.

Copying to a USB Device

You can make a copy of the movies or snapshots taken during a procedure by moving them to a removable storage device. For more details regarding downloading of recordings, see Managing Recordings section on page 45.

To copy to a USB:

1. Insert a USB device into one of the computer's USB ports (located in the front and in the back of the CCU).
2. From the Browser pane, select the movie, or folder of movies, that you want to copy.
3. Click the Copy to USB button 

located underneath the Browser pane.

Viewing a Recorded Movie or Snapshot Stored on a USB

1. Movies and snapshots recorded using the **VS$_3$** and which were downloaded onto a removable storage device can be played back directly from that storage device.
2. The movie or snapshot of the recorded procedure is displayed on the stereoscopic monitor.
3. A single movie or all of the available movies can be played sequentially.

As a safety precaution, a movie or snapshot cannot be played back as long as a camera is connected to the system.

Caution

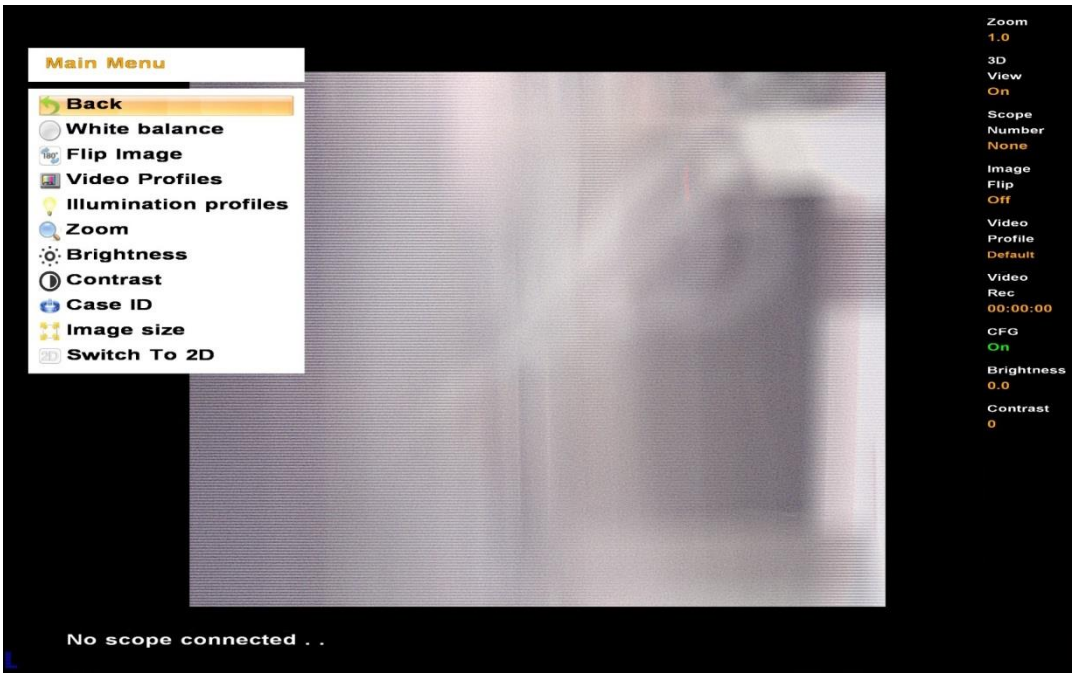
- Before viewing the movie or snapshot in 3D, make sure that you are wearing the provided polarizing glasses.

Deleting Movie Files

You cannot delete movie files. Deleting movie files can only be performed by a Visionsense Technician.

Menu options with Camera Connected

When the camera is connected to the system, the screen and Main menu look like this:



Until you connect the endoscope to the camera, a **No scope connected..** message is displayed at the bottom of the screen.

When the camera is connected to the system, you can perform the following:

- Use the Main menu options to control the image size, rotation, 3D/2D display, and image quality factors.
- Use the buttons on the camera to record a procedure, or take a snapshot.

White Balance

Click on **White Balance** in the **Main Menu** to while pointing the endoscope at a pure white surface located approximately 3cm from the tip of the endoscope to color balance the camera.

Important: White Balance should be done every time you change endoscopes.

Rotating (Flipping) the Image

You can flip the image horizontally by clicking “Flip Image” from the Main menu.

Video Profiles

Video profiles allow you to choose the image display characteristics that best suit a particular surgical field.

To choose a Video Profile:

1. Click the **Distal Button** to display the **Main Menu** and continue clicking to scroll to the **Video Profile** option. Click the middle button to select it. A list of Video Profiles appears - (**example for reference only – may differ than actual menu**):

2. Choose any of the available profiles; the profile loads and you are returned to the **Main Menu**.

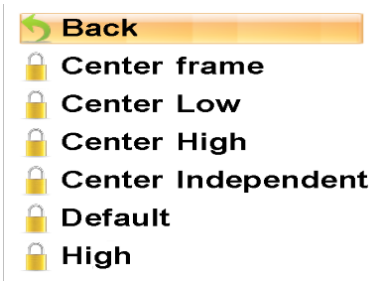
Changing the illumination Profile

If the image center is darker than desired, or if you are working in a narrow space, you can change the illumination profile to best suit your situation.

You can adjust the illumination intensity by changing the Illumination Profile.

To choose an Illumination Profile:

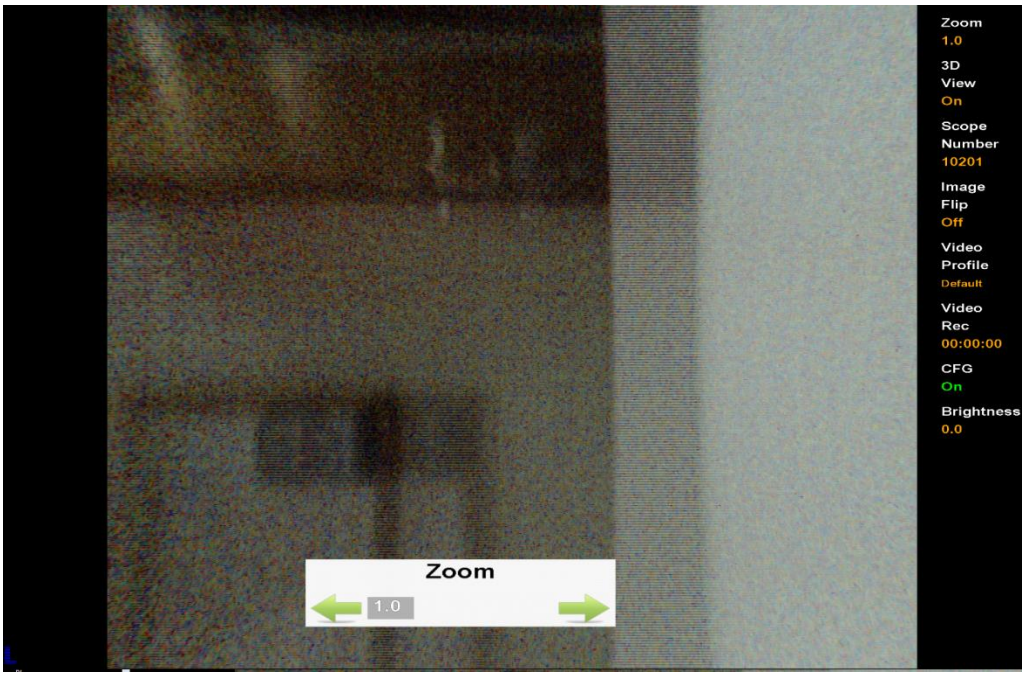
1. Click the Distal Button to display the **Main Menu** and select **Illumination Profile**. A list of illumination profiles appears - (example for reference only – may differ than actual menu):



2. Choose any of the available preferences to load it.
3. After the preference loads, click the **Back** button to return to the **Main Menu.**

Zoom

You can enlarge the image that you are viewing by choosing Zoom from the **Main Menu**. The following display appears:



To zoom in and out of the image, click the distal and proximal buttons on the endoscope (or left and right buttons of the mouse). The zoom increments/decrements by intervals of 0.1, from x1 to x2.

Brightness

This feature allows you to control the brightness of the image directly. By default, the brightness is set to 0.0 and can be increased or decreased.

Contrast

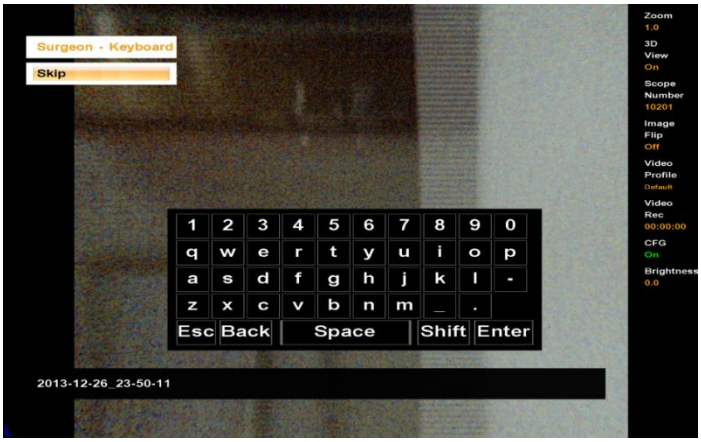
This feature allows you to control the contrast of the image directly. By default, the contrast is set to 0.0 and can be increased or decreased.

Case ID

You can use Case ID to associate with the folder that will contain the subsequent movies or snapshot that you wish to record. All subsequent movies and snapshots will be saved in the specified folder until you use Case ID to specify a new name.

To specify a new name:

1. From the **Main Menu,** choose **Case ID**. The following screen appears:

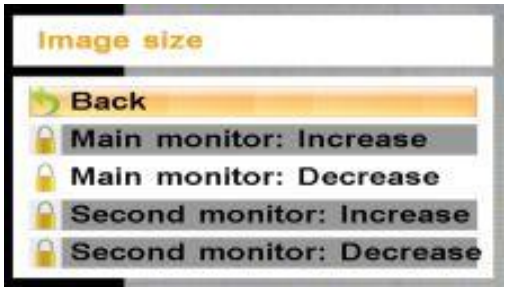


2. Using the touchpad, click Back on the on-screen keyboard repeatedly to erase the displayed name.
3. Using the touchpad, click the appropriate keys on the on-screen keyboard to type the new name.
4. Click the green check to apply the changes. All subsequent movies and snapshots will be saved in the specified folder.

Image Size

The physician/surgeon can change the size of the image on the screen:

- **Increase** will increase the image up to full screen on the main or second monitor.
- **Decrease** will decrease the size down to a preset minimal size on the main or second monitor.



<u>Important</u> - The saved settings become the default for next system restart.

- When using 24” secondary monitor, the changes set for the main monitor are set automatically to the second monitor respectively. The second screen cannot be set independently.
- When using 46” secondary monitor, the changes are set to each monitor independently.

Switch to 2D

Allows you to toggle between 2D and 3D view.

Settings Status Bar

The settings status bar automatically appears on the right side of the screen and displays any time the camera distal button is pressed. The status bar provides the current value of system settings and is used strictly for information.

The status bar is automatically hidden after 10 seconds. Any non-default setting will remain displayed on the status bar.

To display the status bar again press the distal button on the scope.

Settings Status Bar details:

Zoom	Describes the Zoom level of the current view. Default value is 1.0
3D View	Current 3D view setting (ON = 3D mode, Off = 2D mode)
Scope Number	Displays the S/N of the Scope Connected represented by the first 4 digits. Last digit displays the position of the Light Post (*1=light post facing up, 2= light post facing down*). For Example, Scope Number 10201 means current scope S/N is 1020, and it is connected to the camera with the Light Post facing upwards.
Image Flip	Describes Image flip settings (On / Off)
Video Profile	Describes selected Video Profile. Default profile is “Default”.
Video Rec	Displays the Total time recorded from beginning of the session
CFG	Displays the status of the configuration for the current camera and scope. A green “On” means that all configuration settings are loaded. In case a specific setting is missing, it will be written under the CFG icon.
Brightness	Displays the current brightness setting (Default is 0.0)
Contrast	Displays the current contrast setting (Default is 0)

Chapter Five

Maintenance of the VS_3 System

Changing the Endoscope and/or Camera

If the endoscope or the camera becomes contaminated, it is necessary to replace the endoscope or camera with another stand-by device that has been installed for the **VS_3** System and is sterilized. See **Installing a new endoscope** below.

To change an Endoscope, follow these steps:

1. Press the camera attachment spring to release the Endoscope.
2. Detach the endoscope and release the attachment spring of the camera.
3. Press the attachment spring on the camera again.
4. Insert the new (installed) Endoscope into its position
5. Continue with the procedure.

To change a camera, follow these steps:

1. Disconnect the old camera by pulling back the camera connector sleeve until fully retracted and then pulling the cable.
2. Replace the cap to the connector end.
3. Unscrew the cap off the new camera connector.
4. Connect the new camera.
5. Continue with the procedure.

Installing a new endoscope for the first time

Initial installation is required when receiving a new endoscope from Visionsense.
It will be supplied with a USB flash device containing the configuration files for the endoscope. This process needs to be done only once for each system the endoscope is used with.

To install a new endoscope:

1. Connect the endoscope files USB flash device to the system. Make sure the camera <u>is not connected</u> when you connect the endoscope USB flash drive.
2. Click the left touchpad/mouse button to activate the **Main Menu**.
3. In the **Main Menu**, select “**Service**”.
4. In the **Service** menu, select “**Execute Maintenance Script From USB**”. A “quiet” installation will take place.
5. When installation is complete, the message "Camera configuration installed successfully" will appear.

The new endoscope is now installed and ready for use.

Caution

- Do not connect the camera before you connect the USB device and install the files.

Chapter Six

VS_3 Modules and Parts

System Console

The System Console consists of the Camera Control Unit (CCU), Cart and illumination unit.

Camera Control Unit (CCU)

The camera control unit is contains the system's hardware and software required to operate the system.

Input voltage	120 VAC or 230 VAC
Input frequency	50Hz@230VAC or 60Hz@120VAC
Max power consumption	1300VA
Storage Humidity	90%
Operating Humidity	15% to 80% at 35º C
Storage Temperature	-40º C to 70º C
Operating Temperature	10º C to 35º C
Altitude	
Operating:	0 to 3,042m
Non-operating:	0 to 4,572m
Atmospheric Pressure	57.3-106 kPa

Display Unit (Primary Monitor)

The surgical procedure is viewed on the primary monitor which is connected to the System Console. The primary monitor is a Sony 24" stereoscopic display, approved for use in the operating room. An optional 32" Sony monitor is available.

Polarizing Eye Glasses

Polarizing eye glasses enables stereoscopic vision while conducting a surgical procedure. The glasses can be worn on top of regular eye glasses.

Secondary Monitor (optional)

A secondary monitor (stereo or monocular) can be added for extra viewing or educational purposes. A DVI cable is required to connect the secondary monitor.

VSII Endoscope (optional)

The VS_{II} Endoscope provides the physician with natural stereoscopic vision while conducting a surgical procedure. The VS_{II} Endoscope is a fully self-contained device with an integrated distal chip camera and LED light source.

Storage Temperature: -10º C to 70º C; Storage Humidity: 90%

VS3 Endoscope & Camera

The **VS_3** Stereoscopic High Definition System consists of separate **VS_3** Camera and **VS_3** Endoscope units providing the physician with natural stereoscopic vision with enhanced image definition and focus control.

Storage Temperature: -10º C to 70º C; Storage Humidity: 90%

Accessories

Cannula (optional)

You can use a cannula along with the endoscope to keep the endoscope lens clear of debris thereby maintaining maximum vision during a procedure.

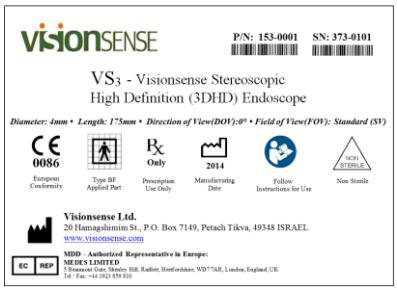
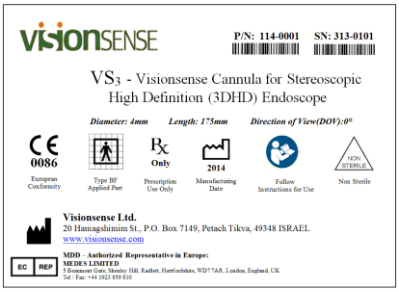
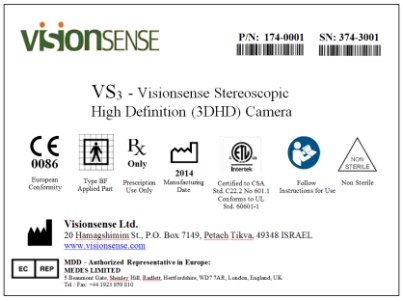
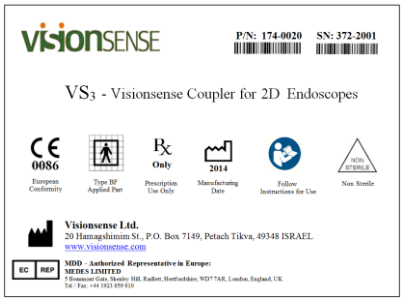
System Power Consumption

Maximum total power consumption 1300W (may be less dependent on display configuration).

Equipment Labels, Symbols, Warning Statements and Abbreviations

Symbol	Explanation
	Ethernet port
	USB Removable Disk port
3D	Stereo Monitor (3D)
	Camera connection port
	On / Off Button
A134°c	Autoclave Approved Camera ID - marked on shaft
	Caution, consult accompanying documents

Symbol	Explanation
	Type "BF" EN 60601-1
	Date of manufacturing
	Separate collection for electrical and electronic equipment, recycling do not dispose into normal waste stream
CE 0086	CE marking of conformity 93/42/EEC & MDD 2007/47
Certified to CSA Std. C22.2 No 601.1 Conforms to UL Std 60601-1 Intertek 4001916	Certified to CSA Std. C22.2 No 601.1 Conforms to UL Std 60601-1
visionSENSE P/N: 143-0001 SN: 343-0301 VS3 - Visionsense Stereoscopic High Definition (3DHD) Vision System 0086 European Conformity; Type BF Applied Part; Rx Only Prescription Use Only; 2014 Manufacturing Date; Certified to CSA Std. C22.2 No 601.1 Conforms to UL Std. 60601-1; Follow Instructions for Use; NON STERILE Non Sterile Visionsense Ltd. 20 Hamagshimim St., P.O. Box 7149, Petach Tikva, 49348 ISRAEL www.visionsense.com EC REP MDD - Authorized Representative in Europe: MEDES LIMITED 9 Beaumont Gate, Shenley Hill, Radlett, Hertfordshire, WD7 7AR, London, England, UK Tel / Fax: +44 1923 859 810 100-120VAC 50/60Hz Max 1500VA	**VS3** Console Label (120V)
visionSENSE P/N: 143-0002 SN: 343-0301 VS3 - Visionsense Stereoscopic High Definition (3DHD) Vision System 0086 European Conformity; Type BF Applied Part; Rx Only Prescription Use Only; 2014 Manufacturing Date; Follow Instructions for Use; NON STERILE Non Sterile Visionsense Ltd. 20 Hamagshimim St., P.O. Box 7149, Petach Tikva, 49348 ISRAEL www.visionsense.com EC REP MDD - Authorized Representative in Europe: MEDES LIMITED 9 Beaumont Gate, Shenley Hill, Radlett, Hertfordshire, WD7 7AR, London, England, UK Tel / Fax: +44 1923 859 810 220-240VAC 50/60Hz Max 1500VA	**VS3** Console Label (230V)

Symbol	Explanation
	**VS$_3$** Endoscope label
	**VS$_3$** Cannula label
	**VS$_3$** Camera label
	**VS$_3$** Coupler for 2D Endoscopes label

List of VS3 Endoscopes and Accessories

Device/Accessories Name	Device Part Number (P/N)	Printing on Endoscope	Ring Color
Endoscope 4mm, Short, 0°, Standard FOV	153-0001	S/N + SV	Green
Endoscope 4mm, Short, 30°, Standard FOV	153-0002	S/N + SV	Red
Endoscope 4mm, Short, 0°, Wide FOV	153-0003	S/N + WV	Green
Endoscope 4mm, Short, 30°, Wide FOV	153-0004	S/N +WV	Red
Endoscope 4mm, Short, 0°, Extended FOV	153-0005	S/N + EV	Silver
Endoscope 4mm, Elbow, Short, 0°,Wide FOV	153-0006	S/N + WV	Green
Endoscope 4mm, Long, 0°, Standard FOV	153-0011	S/N + SV	Green
Endoscope 4mm, Long, 30°, Standard FOV	153-0012	S/N + SV	Red
Endoscope 4mm, Long, 0°, Wide FOV	153-0013	S/N +WV	Green
Endoscope 4mm, Long, 30°, Wide FOV	153-0014	S/N +WV	Red
Endoscope 5.5mm, Short, 0°, Standard FOV	153-0021	S/N + SV	Green
Endoscope 5.5mm, Short,30°, Standard FOV	153-0022	S/N + SV	Red
Endoscope 5.5mm, Short, 0°, Wide FOV	153-0023	S/N +WV	Green
Endoscope 5.5mm, Short, 30°, Wide FOV	153-0024	S/N +WV	Red
Endoscope 5.5mm, Long, 0°, Standard FOV	153-0031	S/N + SV	Green
Endoscope 5.5mm, Long, 30°, Standard FOV	153-0032	S/N + SV	Red
Endoscope 5.5mm, Long, 0°, Wide FOV	153-0033	S/N +WV	Green
Endoscope 5.5mm, Long, 30°, Wide FOV	153-0034	S/N +WV	Red
ETV Endoscope 6mm, Short, 0°, Wide FOV	153-0041	S/N +WV	Green
Cannula 4mm, Short, 0°	114-0001	S/N	Green
Cannula 4mm, Short, 30°	114-0002	S/N	Red
Cannula 4mm, Long, 0°	114-0011	S/N	Green
Cannula 4mm, Long, 30°	114-0012	S/N	Red
Cannula 5.5mm, Short, 0°	114-0021	S/N	Green
Cannula 5.5mm, Short, 30°	114-0022	S/N	Red
Cannula 5.5mm, Long, 0°	114-0031	S/N	Green
Cannula 5.5mm, Long, 30°	114-0032	S/N	Red
High Definition Stereoscopic (3DHD) Camera	174-0001	S/N	N/A
Coupler for 2D Endoscopes (“2D Coupler”)	174-0020	S/N	N/A
Coupler for Large 2D Endoscopes (“2D Coupler Large”)	174-0021	S/N	N/A

List of VS_{II} Cameras and Cannulas

Device/Accessories Name	Device Part Number (P/N)	Label on Cable	Buttons Color
Camera Rigid, Short, Standard View, 0°	172-0030	S/N	Black
Camera Rigid, Short, Standard View, 30°	172-0031	S/N	Black
Camera Rigid, Long, Standard View, 0°	172-0032	S/N	Black
Camera Rigid, Long, Standard View, 30°	172-0033	S/N	Black
Camera Rigid, Short, Wide View, 0°	172-0070	S/N	Orange
Camera Rigid, Short, Wide View, 30°	172-0071	S/N	Orange
Camera Rigid, Long, Wide View, 0°	172-0072	S/N	Orange
Camera Rigid, Long, Wide View, 30°	172-0073	S/N	Orange
Camera Rigid, Short, Standard View, 0°,Demo	172-0040	S/N + DEMO	Black
Camera Rigid, Short ,Standard View,30°,Demo	172-0041	S/N + DEMO	Black
Camera Rigid, Long, Standard View, 0°, Demo	172-0044	S/N + DEMO	Black
Camera Rigid, Long, Standard View, 30°,Demo	172-0045	S/N + DEMO	Black
Camera Rigid, Short, Wide View, 0°, Demo	172-0080	S/N + DEMO	Orange
Camera Rigid, Short, Wide View, 30°, Demo	172-0081	S/N + DEMO	Orange
Camera Rigid, Long, Wide View, 0°, Demo	172-0082	S/N + DEMO	Orange
Camera Rigid, Long, Wide View, 30°, Demo	172-0083	S/N + DEMO	Orange
Camera Rigid, Short, Standard View, 0°, Autoclaveable	172-0230	S/N	Black
Camera Rigid, Short , Standard View, 30°, Autoclaveable	172-0231	S/N	Black
Camera Rigid, Long, Standard View, 0°, Autoclaveable	172-0232	S/N	Black
Camera Rigid, Long, Standard View, 30°, Autoclaveable	172-0233	S/N	Black
Camera Rigid, Short, Wide View, 0°, Autoclaveable	172-0270	S/N	Orange
Camera Rigid, Short, Wide View, 30°, Autoclaveable	172-0271	S/N	Orange
Camera Rigid, Long, Wide View, 0°, Autoclaveable	172-0272	S/N	Orange
Camera Rigid, Long, Wide View, 30°, Autoclaveable	172-0273	S/N	Orange
Camera Rigid, Short, Standard View, 0°, Demo, Autoclaveable	172-0240	S/N + DEMO	Black
Camera Rigid, Short , Standard View, 30°,Demo, Autoclaveable	172-0241	S/N + DEMO	Black
Camera Rigid, Long, Standard View, 0°, Demo, Autoclaveable	172-0242	S/N + DEMO	Black
Camera Rigid, Long, Standard View, 30°, Demo, Autoclaveable	172-0243	S/N + DEMO	Black
Camera Rigid, Short, Wide View, 0°, Demo, Autoclaveable	172-0280	S/N + DEMO	Orange
Camera Rigid, Short, Wide View, 30°, Demo,	172-0281	S/N + DEMO	Orange

Device/Accessories Name	Device Part Number (P/N)	Label on Cable	Buttons Color
Autoclaveable			
Camera Rigid, Long, Wide View, 0°, Demo, Autoclaveable	172-0282	S/N + DEMO	Orange
Camera Rigid, Long, Wide View, 30°, Demo, Autoclaveable	172-0283	S/N + DEMO	Orange
Camera Rigid, Short, Standard View, 0°, Not for Human Use	172-0042	S/N + N4HU	Black
Camera Rigid, Short , Standard View, 30°, Not for Human Use	172-0043	S/N + N4HU	Black
Camera Rigid, Long, Standard View, 0°, Not for Human Use	172-0046	S/N + N4HU	Black
Camera Rigid, Long, Standard View, 30°, Not for Human Use	172-0047	S/N + N4HU	Black
Camera Rigid, Short, Wide View, 0°, Not for Human Use	172-0084	S/N + N4HU	Orange
Camera Rigid, Short, Wide View, 30°, Not for Human Use	172-0085	S/N + N4HU	Orange
Camera Rigid, Long, Wide View, 0°, Not for Human Use	172-0086	S/N + N4HU	Orange
Camera Rigid, Long, Wide View, 30°, Not for Human Use	172-0087	S/N + N4HU	Orange
Cannula for Camera Rigid Short, 0°	110-0003	N/A	N/A
Cannula for Camera Rigid Short, 30°	110-0004	N/A	N/A
Cannula for Camera Rigid Long, 0°	110-0005	N/A	N/A
Cannula for Camera Rigid Long, 30°	110-0008	N/A	N/A
Camera Flexible, Standard View , 0°	173-0030	S/N	Black
Camera Flexible, Wide View, 0°	173-0070	S/N	Orange
Camera Flexible, Standard View , 0°, Demo	173-0040	S/N + DEMO	Black
Camera Flexible, Wide View, 0°, Demo	173-0080	S/N + DEMO	Orange
Micro Holder for Flexible Endoscope	113-0001	N/A	N/A
Hand Holder for Flexible Endoscope	113-0002	N/A	N/A

Chapter Seven

Troubleshooting

The following messages are displayed by the **VS_3** system. When a message is displayed, check the recommended action below:

Error Message	**What to do**
Camera not recognized! Please replace camera and notify support.	Try replacing the camera with one that has been properly installed. (See Changing the camera section on page 54.) If the message persists even after replacing the camera, stop work and call technical support for servicing.
Scope not recognized! Please replace scope and notify support.	Try replacing the Endoscope with one that has been properly installed. (See Changing the Endoscope section on page 54.) If the message persists even after replacing the Endoscope, stop work and call technical support for servicing.
No camera connected	This message normally appears when no camera is connected to the system. In case the message is displayed after the camera had been connected, try the following: ● Check to see whether the camera was connected correctly. ● If the message still displays, replace the camera and notify support.
No scope connected	This message normally appears when the **VS_3** camera is connected, but no endoscope is connected to the camera. In case the message is displayed after the scope had been connected, try the following: ● Check to see whether the scope was connected correctly. ● If the message still displays, replace the scope and notify support.
System failure. Please contact support.	If camera is connected, try to reconnect the camera. If camera is not connected, stop operation and call support.
Camera communication check cables error.	Restart the system. If the message still displays, call Visionsense support.

The following table is a general troubleshooting guide:

Description	What to do
No image is displayed on screen or Blank Screen.	1. Make sure the system is connected to the electrical outlet, and turned on (both the PC and the display). 2. Check that all the cables are securely connected. 3. Press the On/Off button once to start the system in case it is turned off. 4. Disconnect the camera from the system. The message ‘no camera connected’ should appear. If there is still no image on the screen (not even background image) stop operation and call support.
Left eye image is displayed to the right eye and vice versa	Verify that the correct eye is displayed using the built in stereo test: a small "L" should appear on the bottom left side of screen **ONLY** on your left eye. Make sure you are aligned to the monitor at eye level.
No stereo image is displayed (Blue L appears on both eyes/ does not appear at all)	Shut down and restart the system. If the problem persists, contact support.
The image is flipped upside down	Click the Distal camera button to access the menu. Click the Distal button to scroll to "flip image". Click the Middle button to flip image.
One of the eyes is flipped, and the other is shown correctly. Image is fuzzy.	Make sure you are using the polarized glasses to view the monitor. If the problem persists, contact a Visionsense representative for support.
Camera or scope dropped	Check to see if image remains. Retained image shows no sign of damage.

Chapter Eight

Electromagnetic Testing And Compatibility

Electromagnetic Compatibility – Manufacturer Declaration

Notes

- The VS_3 System requires special precautions with regard to electromagnetic compatibility.
- The system must be installed and prepared for use as described in this manual.
- Certain types of mobile telecommunication devices such as mobile telephones are likely to interfere with the VS_3 System.
- The recommended separation distances in this paragraph must be complied with.
- The VS_3 System must not be used near or on top of another device. If this cannot be avoided, it is necessary – before clinical use – to check the equipment for correct operation under the conditions of use.
- The use of accessories other than those specified or sold by VISIONSENSE as replacement parts may have the consequence of increasing the emissions or decreasing the immunity of the unit.

Electromagnetic Emissions

- VS_3 System is intended for use in the electromagnetic environment specified in the following tables 1, 2, 4 and 6 below.
- The user and/or installer of the unit must ensure that it is used in such an environment.

Table 1		
Guidance and manufacturer's declaration – electromagnetic emissions – VS_3 System		
The **VS_3 System** is intended for use in the electromagnetic environment specified below; The customer or the user of the **VS_3 System** should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The **VS_3 System** uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The **VS_3 System** is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table 2			
Guidance and manufacturer's declaration – electromagnetic immunity – VS_3 System			
The **VS_3 System** is intended for use in the electromagnetic environment specified below; The customer or the user of the **VS_3 System** should assure that it is used in such an environment.			
Immunity test	**IEC 60601-1-2** **Test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or Ceramic tile. If floors are covered with synthetic material, the relative humidity Should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines Not Applicable	Mains power quality should be that of a typical public low-voltage power supply network that supplies buildings used for domestic purposes, commercial or hospital, clinic environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical public low-voltage power supply network that supplies buildings used for domestic purposes, commercial or hospital, clinic environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 .	<5 %UT (>95 %dip in UT) for 0,5 cycle 40 %UT (60 %dip in UT) for 5 cycles <5 %UT 70 %UT (30 %dip in UT) for 25 cycles <5 %UT	<5 %UT (>95 %dip in UT) for 0,5 cycle 40 %UT (60 %dip in UT) for 5 cycles <5 %UT 70 %UT (30 %dip in UT) for 25 cycles <5 %UT	Mains power quality should be that of a typical public low-voltage power supply network that supplies buildings used for domestic purposes, commercial or hospital, clinical environment. If the user of the **VS_3 System** requires continued operation during power mains interruptions; it is recommended that **VS_3 System** be powered from a separate power supply (UPS, etc.).

	<5 %UT (>95 %dip in UT) for 5 s	<5 %UT (>95 %dip in UT) for 5 s	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical public low-voltage power supply network that supplies buildings used for domestic purposes, commercial or hospital, clinic environment.
NOTE: UT is the a.c. mains voltage prior to application of the test level.			

Table 4			
Guidance and manufacturer's declaration – electromagnetic immunity – VS_3 System			
The **VS_3 System** is intended for use in the electromagnetic environment specified below; The customer or the user of the **VS_3 System** should assure that it is used in such an environment.			
Immunity test	**IEC 60601-1-2** **Test level**	**Compliance level**	**Electromagnetic environment – guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the **VS_3 System**, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted RF IEC 61000-4-6	3 Vrms 150 k Hz to 80 MHz	3 Vrms	**Recommended separation distance** $d = 1.17\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = 1.17\sqrt{P}$ 80 M Hz t o 800 MHz $d = 2.3\sqrt{P}$ 800 MHz t o 2,5 GHz where P i s the maximum output power rating of the transmitter in watts (W)according to the transmitter manufacturer and d i s the recommended separation Distance in meters (m). Field strengths from fixed R F transmitters, as determined by an electromagnetic site survey ,[a] should be less than t he compliance level in each frequency range .[d] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations .Electromagnetic propagation is affected by absorption And reflection from structures objects and people.
A Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the **VS_3 System** is used exceeds the applicable RF compliance level above, the **VS_3 System** should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the **VS_3 System**. B Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended Separation Distances

The VS_3 System is intended for use in an electromagnetic environment in which radiated radiofrequency disturbances are controlled.

The user and/or installer of the unit can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile radiofrequency communications equipment (emitters) and the VS_3 System, according to the maximum output power of the equipment, as recommended in the table below.

Table 6

Recommended separation distances between portable and mobile RF communications equipment and the VS_3 System

Rated maximum output power of transmitter Watts [W]	Separation distance according to frequency of transmitter (in meters) Meters [m]		
	150kHz to 80MHz $d = 1.17\sqrt{P}$	80MHz to 800MHz $d = 1.17\sqrt{P}$	800MHz to 2.5GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23

0.1	0.37	0.37	0.73
1	1.17	1.17	2.3
10	3.7	3.7	7.3
100	11.7	11.7	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m)

can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power

rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Table 6a

Recommended separation distances between

Power bus or an appliance wire and the VS_3 System

Rated maximum current (I) in a power bus or an appliance wire	**Separation distance (in meters)**	
	Meters [m]	
Amperes [A]	R = I/2πH=I/18.8	
0.1	0.005	
1	0.05	
10	0.5	
100	5.3	
1000	53	

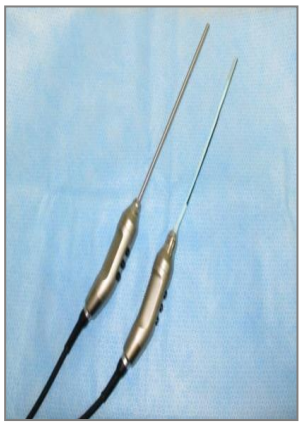
NOTE 1 The power frequency magnetic field immunity of H=3 A/m is met.

Appendix A:
VS_{II} Endoscope (optional)

The VS_{II} Endoscope Module (optional)

The VS_3 system has been specifically designed to be fully compatible with the VS_{II} Endoscope and allow full functionality when using the VS_{II} Endoscope.

The **VS_{II}** stereoscopic endoscope features a rigid or flexible laparoscope unit that contains the camera and illumination unit *internally*, unlike standard laparoscopes



The VS_{II} Endoscope (Rigid or Flexible) includes:

- A distal camera to capture the images
- A proximal handle that includes the LED illumination and three programmable control buttons.
- A fiber bundle to relay light from the handle to the scene.
- Video cable, connecting to the **VS_3** System.
- Rigid Endoscope – with stainless steel shaft.
- Flexible Endoscope – with bendable fibers.

To begin procedures, the endoscope cable should be connected to the Camera Control Unit (CCU). This will activate all functionality in the VS_{II} endoscope.

Cleaning and Sterilizing the VS_{II} Endoscope

The **VS_{II}** endoscope must be cleaned and sterilized before being used in a surgical procedure. The following sections describe the materials and procedures required for the cleaning and sterilization processes:

- Materials Required for Cleaning and Sterilization
- Cleaning the Endoscope
- Sterilizing and Handling the Endoscope

Note: For questions regarding the cleaning and sterilization process, contact Customer Support (contact details on page 8).

Materials Required for Cleaning and Disinfection or Sterilization

The authorized clinic/hospital personnel will need the following materials to carry out the processes of cleaning and sterilizing the **VS_{II}** endoscopes:

- Cleaning agents:

- Enzymatic Detergent[5]
- Non-Enzymatic Detergent[6]
- Any cleaning solution that is approved by your institution's protocol for endoscopic equipment - **See the following Cautions:**

Cautions

- **Cleaning agents must state Aluminum Suitability by the manufacturers**
- **Cleaning agents should be up to pH=10.0**

- Tap water
- Sterile water
- Large water basin (approximately 40cm X 40cm X 20cm)
- Scrub brush (such as the "3M brush team")
- Sterile gauze pads
- Sterile, no powder gloves
- Protective attire according to institutional protocol
- Endoscope and protective cap
- Sterilization box

Cleaning the VS_{II} Endoscope (Rigid and Flexible)

Both new endoscopes and those previously used in a procedure must be cleaned before disinfection or sterilization. When the physician/surgeon has finished using an endoscope, it must be promptly prepared for cleaning by the authorized personnel.

MANDATORY - Prior to any cleaning or immersing, make sure to cover the male part of the medical connector attached to the endoscope's main cable with the protective cap and to properly tighten the cap.

Note: The protective cap is intended to secure the connector throughout the entire cleaning and sterilization reprocessing and therefore must remain closed until usage.

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[5] ENDOZIME®, RUHOF CORP. Enzymatic Detergent was validated for cleaning efficacy

[6] RENU-KLENZ®, STERIS CORP. Non-Enzymatic Detergent was validated for cleaning efficacy

Cautions

- Failure to cover the endoscope's connector will result in irreparable damage to the endoscope.
- Ultrasonic cleaning methods **are prohibited** when cleaning or sterilizing the endoscope or Light Guide.
- Do not pull on the cable connected to the rigid end of the endoscope.

Manual cleaning of VS_{II} Rigid and Flexible Endoscope:

1. Verify that the protective cap is attached to the medical connector of the endoscope main cable. Do not try to immerse the unit without attaching the cap.
2. Rinse the endoscope in warm tap water to remove any tissue debris and/or bloody residue.
3. Use approved cleaning solutions to remove resistant debris.
4. Thoroughly rinse off all soap residue.
5. Dry thoroughly. Do not remove the protective cap.

Automated cleaning of VS_{II} Rigid Endoscope and Cannula:

1. Verify that the protective cap is attached to the medical connector of the endoscope main cable. Do not try to clean the unit without attaching the cap.
2. Rinse the VS_{II} Rigid Endoscope and Cannula in warm tap water to remove any tissue debris and/or bloody residue.
3. Place the endoscope and cannula in the sterilization tray. Make sure that the Endoscope is properly fixated in the sterilization tray. Place the distal part of the Endoscope (shaft) through the silicon fixation opening and the proximal part of the Endoscope between the silicon fixations (see figure below). Make sure the excess cable and connector are placed behind the Endoscope's handle. For ultimate cleaning, do not place the knobs of the Endoscope's handle in contact with the silicone fixation
4. Use the automated washer according to hospital protocol for using such a cleaner.
5. Store the dry Endoscope and Cannula. Do not remove the protective cap.

After the cleaning has been completed, the Endoscope and/or Cannula can be stored or disinfected/sterilized for immediate use.

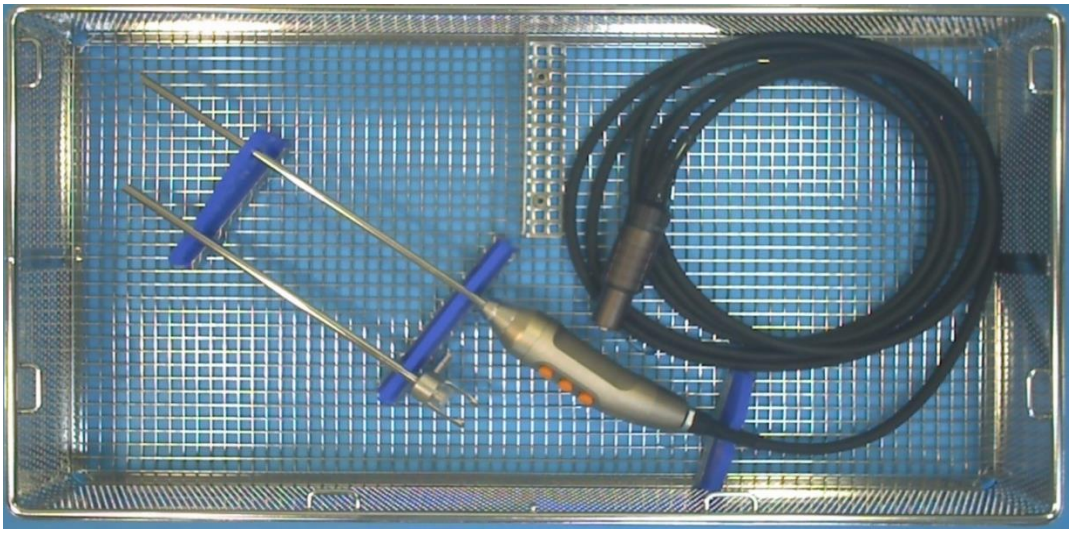

Figure 13: Endoscope and Cannula

Cleaning the VSII Cannula

VS_{II} Cannulas are reusable and must be thoroughly cleaned after each use to remove contaminating substances prior to sterilization.

Manual cleaning of the Cannula:

1. Rinse the Cannula in warm tap water to remove any tissue debris and/or bloody residue.
2. Remove temporarily the grommet.
3. Clean thoroughly the Cannula and grommet with a mild soapy solution.
4. Use appropriate brushes for cleaning the cannula including the lumen.
5. Run cleaning solution through lumen.
6. Dry thoroughly the entire cannula, including the lumen.
7. Attach back the grommet on proximal side of Cannula.
8. Cleaned Cannula should be wrapped prior to sterilization with cotton cloth.
9. Complete preparation for sterilization in accordance to hospital's approved protocol.

Note: on first use of new Cannula start cleaning process from step (2).

Automated wash of the Cannula:

See "Automated cleaning of the VS_{II} Rigid Endoscope and Cannula" on page 78.

Terminally Sterilizing the VSII Endoscope

The **VS_{II}** endoscopic equipment is supplied non-sterile and must be terminally sterilized by authorized clinic/hospital personnel prior to use. In the current version of the **VS_{II}** System, authorized personnel can sterilize the **VS_{II}** endoscope unit using low temperature sterilization processes, such as STERRAD® (STERRAD® 50/100S/200/NX/100NX Systems).

Visionsense Autoclave approved endoscopes are marked on the shafts with "A134°c". Autoclave approved endoscopes are approved for autoclave processing at 134°c for at least 6 minutes.

Autoclave approved cameras should be autoclaved in accordance with the hospital protocols, yet should meet the processing specifications mentioned above.

Important: Before performing the cleaning or autoclave process it is mandatory to verify that the camera's connector protective cap is properly tightened in place.

Cautions

Note the following precautions prior to sterilizing the VS_{II} endoscope:

- Do not sterilize the endoscope via gamma irradiation

- Do not perform autoclave sterilization for **VS_{II}** cameras that are not marked by "A134°c" on its shaft as autoclave approved. This can damage the camera irreversibly!

- Do not perform autoclave sterilization for **Flexible** VS_{II} endoscope**.** This can damage the Endoscope irreversibly!

- Follow manufacturer instructions for sterilization.

- Do not use cleaning and/or sterilization processes that have not been validated.

- In order to help prevent Health Care Associated Infections (HAI) do not use cleaning or sterilization processes that have not been validated including automated washers, immediate use (flash) sterilization, etc. For more information on HAI please reference "Rutala, W.A., Weber D. J., & HICPAC. (2008). Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008. Atlanta, GA"; available at Centers for Disease Control web site www.cdc.gov .

Warning

- Do not remove the protective cap before cleaning – not even during the transition between cleaning and sterilizing. Removing the protective cap may result in a contaminated device. Only authorized personnel outside the sterile zone should remove the protective cap prior connecting the Camera's connector to the Camera Control Unit (CCU).

- This device is used in the neurosurgical field where there is a high-infectivity risk of Creutzfeldt-Jakob disease (a.k.a. TSE, CJD) or similar prions in patients who are known or suspected to be infected. Dispose or destroy devices that have been used on patients suspected of having Creutzfeldt-Jakob disease or other prion diseases according to the WHO guidelines, unless sterilizing the devices with STERRAD 100NX Standard Cycle process which is currently thought to eradicate prions. This device is fabricated of materials which can withstand the reprocessing exposure conditions of STERRAD 100NX sterilization. To learn more about this disease you may wish to consult the WHO guidelines - World Health Organization's 1999 guidance document (Infection Control Guideline for Transmissible Spongiform Encephalopathies. Geneva, Switzerland).

- The qualified ASP STERRAD® Sterilization Systems are: STERRAD® 50, 100S, 200, NX Standard Cycle, and 100NX, Standard and DUO Cycles only (100NX Express Cycle is not qualified). Please refer to ASP/ STERRAD® System User's Guide for the appropriate cycle in each STERRAD® system for the instrument to be reprocessed. All instruments must be cleaned, rinsed, and thoroughly dried prior to placement in a STERRAD® sterilizer.

Terminally Sterilizing the VSII Cannula

The Cannula (with grommet) should be autoclaved at a temperature of 121°C (250°F) to 132°C (270°F) for 20 minutes.

Note: In any case of contraindications, the hospital's policy and/or procedures may take precedence over this protocol.

Caution: Federal Law restricts this device to sale by or on the order of a licensed physician or healthcare provider.