

Endoscopic Surgical System

3D Endoscope

BEFORE USING THE PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

IMPORTANT!

This booklet is designed to assist in using this product. It is not a reference to surgical techniques.

DESCRIPTION

The 3D endoscope is used to collect surgical image signal, then the signal is processed by the visual processing workstation and then transmitted to the Surgeon Console. The 3D endoscope is controlled by the SHURUI® Endoscopic Surgical System. For the SHURUI® Endoscopic Surgical System configuration information, instructions for use, indications, contraindications, warnings and precautions, please refer to the SHURUI® Endoscopic Surgical System User Manual.

COMPATIBILITY

The 3D endoscope is only compatible with the SHURUI® Endoscopic Surgical System (SR-ENS-600).

Description	Model
3D Endoscope	SR-ENP-SP1001

INTENDED PURPOSE / INTENDED USE

The SHURUI® 3D Endoscope is controlled by the SHURUI® Endoscopic Surgical System for endoscopic surgical operations through a single port. The 3D Endoscope is intended to provide stereoscopic imaging and illumination, enabling surgeons to perform minimally invasive endoscopic surgery with the SHURUI® Endoscopic Surgical System. It is intended for use by trained surgeons in an operating room environment in accordance with the representative, specific procedures set forth in the SHURUI® Endoscopic Surgical System User Manual.

WARNINGS AND PRECAUTIONS

1. Thermal hazards may exist from high temperatures. Eye hazards may exist from the high-energy light radiated by the endoscope and illumination system. Only personnel having adequate training and experience with the endoscope and illumination system should operate such equipment. All warning and caution messages provided with the endoscope and illumination system must be followed.
2. After disconnecting the illuminating optical fiber, the user should take care to avoid coming into contact with the hot optical fiber connector on the 3D endoscope.
3. The temperature of the vision module may exceed 41°C due to prolonged use of the 3D endoscope.
4. Do not modify the 3D endoscopes. Modifications can result in electrical hazards or performance degradation.
5. Before using the 3D endoscope, its sterility should be checked.
6. Before use, check whether the 3D endoscope has abnormal conditions such as stem bending, sharp edges, cracks, dents, corrosion, or mechanical defects, and avoid using 3D endoscope with the abnormal conditions.
7. Do not clean the vision module of the 3D endoscope with other instruments during surgery. Otherwise the vision module may be damaged. If the vision module needs cleaning, remove the 3D endoscope from the patient's

body, clean the vision module with iodophor carefully and wipe it dry with gauze.

8. Any serious incident that has occurred in relation to this device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

9. For reprocessing instructions of the 3D endoscope, please refer to the 3D Endoscope Reprocessing Instructions.

INTRAOPERATIVE USE

For instructions on installing, removing, and using the 3D endoscope with the SHURUI® Endoscopic Surgical System, please refer to the SHURUI® Endoscopic Surgical System User Manual.

REPROCESSING LIMITATIONS

The 3D endoscope has restrictions on the number of uses. The service life of the 3D endoscope is described in the SHURUI® Endoscopic Surgical System User Manual.

The SHURUI® Endoscopic Surgical System will pop up alarm when the 3D endoscope with the usage approaching or reaching the use limit is installed. The maximum number of cleaning and sterilization cycles is the same as the service life.



Non-sterile



Read the user manual
before use



Medical Device



Humidity limitation



Temperature limit



Keep dry



Type CF Applied Part



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File Number: H-15-000109

Version: V4

Date: 2026.01.30