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Hysteroscopes and Gynecologic Laparoscopes

Submission Guidance for a 510(k)

FINAL: March 7, 1996

(Replaces portions of previous: "Hysteroscopes and Laparoscopes, Insufflators & Other Related Instrumentation: Submission Requirements for a 510(k)", dated March 25, 1994)

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Prepared by: Obstetrics-Gynecology Devices Branch
Office of Device Evaluation
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Introduction

This document outlines the information to be submitted in a 510(k) premarket notification for hysteroscopes and gynecologic laparoscopes. For devices that differ significantly from those already on the market, FDA may require additional information specific to those differences. This document is intended as a companion to the Substantial Equivalence Comparison Chart released in April 1995 (see Appendix A), and it replaces our previous March 25, 1994, "Hysteroscopes & Laparoscopes, Insufflators & Other Related Instrumentation: Submission Requirements for a 510(k)."

Due to the diversity in their design and intended use, hysteroscopic/laparoscopic accessories (such as forceps, electrodes, insufflators, light sources, etc.), are not specifically addressed in this guidance document. However, many of the non-electrical accessories are suitable for Tier-1 review (see Appendix B). For more information on the Tier-1 policy, contact the Center for Devices and Radiological Health's Division of Small Manufacturers Assistance (DSMA) at (800) 638-2041 or (301) 443-6597. Information about premarket notification requirements for insufflators may be found in "Hysteroscopic and Laparoscopic Insufflators: Submission Guidance for a 510(k)," also available from DSMA.

For more information, contact DSMA or the:

Obstetrics and Gynecology Devices Branch
Office of Device Evaluation, HFZ-470
9200 Corporate Blvd.
Rockville, MD 20850
(301) 594-1180

I. Device Identification

A. Device Name

Provide both the trade and proprietary name of the instrument, as well as the common or usual name for the particular type. Specify whether the device is: (i) fiberoptic, electronic video (CCD), or rigid rod-lens, (ii) operative or diagnostic, (iii) rigid, flexible, or steerable, and (iv) 2-D or 3-D.

B. Predicate Device Name

Identify the legally marketed devices to which the new device will be compared. Be as specific as possible, e.g., proprietary and common name, manufacturer, model number, 510(k) reference number, pre-Amendments status, etc. The 510(k) should include a tabbed section with product literature (description, specifications & labeling, etc.) for the predicate device.

II. Administrative Information

Establishment Registration number
Contact Person and Title
Telephone number and FAX number

III. Classification: Class II (Special Controls)

Give the CFR classification regulation number for the device, as well as its classification:

Device	Class	CFR Reference	ProCode
· Hysteroscope	II	21 CFR §884.1690	HIH
· Gynecologic Laparoscope	II	21 CFR §884.1720	HET

IV. § 514 Special Controls

Special Controls under §514 of the Act have not been developed for these devices. Reference is made in later sections of this guide to voluntary industry standards.

V. Device Description, Intended Use, and Directions for Use

This section identifies the information necessary to evaluate the hysteroscope/laparoscope's technological characteristics. Additional information may be required depending on the individual design and function of the device.

In order to permit an equivalence determination, all of the device characteristics and performance data presented in the premarket notification should be compared with a legally marketed device whenever possible. (See the "Substantial Equivalence Comparison Chart for Laparoscopes," Appendix A).

A. Intended Use

The 510(k) must provide a clear statement of the device's intended use, including the indications for use. Generic intended use statements are listed below:

Hysteroscope - used to permit direct viewing of the cervical canal and the uterine cavity for the purpose of performing diagnostic and surgical procedures.

Laparoscope - used to permit direct viewing of the organs within the peritoneal cavity for the purpose of performing diagnostic and surgical procedures.

B. Device Description

1. System Block Diagram (if applicable)

2. Schematics and Diagrams

Provide diagrams of the hysteroscope or laparoscope, with all key dimensions and component materials well marked. Multiple diagrams may be necessary to show adequate detail, including key cross-sectional diagrams at distal and proximal ends.

3. Materials

A table listing all patient-contacting materials should be provided. The results of biocompatibility testing performed on the finished device, or certification that identical materials are used in a legally marketed device with a similar intended use, is also required.

For additional information on biocompatibility, please refer to the Blue Book Memorandum "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing'," available from the Division of Small Manufacturers Assistance. Hysteroscopes are considered limited duration surface devices contacting a mucosal membrane or compromised surface. Laparoscopes are considered limited duration external communicating devices contacting tissue/bone/dentin.

C. Safety Requirements

1. Thermal Safety

Due to the use of high-intensity light sources, temperatures at the distal ends of many endoscopes can reach tissue damaging levels. Please provide bench data showing that the device will not present a thermal hazard to the patient. This should consist of plots of temperature versus times for several key locations on the outside of the endoscope, including the tip. Testing should last at least two hours, and should be conducted in room air with the light source set at its maximum intensity setting.

The temperature at any patient-contacting part of the endoscope should not exceed 41°C, except for the distal tip, which should not exceed 50°C. If the temperature at the distal tip exceeds 41°C, the labeling should include a statement warning the user of the potential for thermal injury. See part 42 of the draft standard "Particular requirements for the safety of endoscopic equipment," IEC 601-2-18 (September 1994) for additional details.

2. Electrical Safety

Hysteroscopes and laparoscopes intended to be used with electrosurgical equipment should meet the interconnection test and capacitively coupled HF current requirements (part 42.101) of IEC 601-2-18.

Hysteroscopes and laparoscopes that include an electronic component (e.g., video, signal-processing unit) should also comply with the electrical shock hazard requirements of IEC 601-2-18.

3. Electromagnetic Compatibility (if applicable)

Provide either:

- Certification that the device complies with applicable standards for Immunity and Emissions (such as CISPR 11, IEC 601-1-2); or
- Test results that guarantee a similar level of protection; or
- Justification for why this information is unnecessary (e.g., due to device design or working conditions).

D. Device Components

1. Dimensions

a. Working length
b. Outer diameter
c. Working channel diameter (if applicable)

2. Video camera (if applicable)
(Note: Information on the video camera and video monitor should be included if these items are included in the 510(k))

a. Number of pixels or lines (horizontal)
b. Number of pixels or lines (vertical)
c. Number of pixels used for color

3. Video Monitor (if applicable)

   a. Monitor size (diagonal size, in inches)
   b. Number of lines (horizontal)
   c. Number of lines (vertical)

4. Compatible Light Source

   a. Type of source (e.g., Quartz, Xenon)
   b. Power rating of source (watts)

5. Power supply (if a separate power supply unit is part of the system)

   a. Type
   b. Power requirements (volts, Hz)

E. Optical Performance

1. Objective lens

   a. Focal length or working distance (mm)
   b. Field of view (degrees)
   c. Direction of view from center axis (degrees)

2. Illumination fibers

   Ratio of luminous energy transmitted to energy delivered.

3. Image transmission system (if applicable)
   a. Fiberoptic Imaging Systems (if applicable)

      (1) Total number of fibers/pixels
      (2) Fibers per square millimeter
      (3) Size of fiber core (mm)
      (4) Area of active fiber per square millimeter
      (5) Ratio of luminous energy transmitted to energy delivered

b. Electronic Video Imaging Systems (if applicable)

(1) Total number of pixels
(2) Pixels per square millimeter
(3) Size of pixel (nm)
(4) Active area of CCD chip (mm x mm)

4. Eyepiece (if applicable)

Power or magnification

5. Coupling Lens (if applicable)

Focal length (mm)

6. System

a. Image quality. Provide either:

Resolution. There are several bar patterns available to use as an acceptable method of assessment of device resolution. These bar patterns include the following: (1) USAF bar pattern, (2) NBS 1010A Microcopy Test Chart, or (3) ANSI/ISO Test Chart #2. The test setup should have the bar pattern on the axis and should optimize the magnification and illumination.

or

Modulation Transfer Function (MTF). Provide a description of the system MTF over relevant spatial frequencies. This test setup should have the bar pattern on the axis, and should optimize the magnification and illumination.

b. Distortion characteristics

Provide information on the distortion introduced by the optical system. As an example, this could be provided by imaging a piece of graph paper and providing a comparison of the paper and the photographed image of the graph paper. If the distortion is corrected by signal processing, provide the resulting, corrected image of the graph paper. Include a description of the methods used to measure distortion.

F. Mechanics

The information provided for system mechanics should address changes that occur as a result of sterilization and/or any other reprocessing expected during use.

Provide a description of the mechanics of the laparoscope or hysteroscope, and individual mechanical systems, as applicable:

a. Bending mechanism and its controls
b. Fluid delivery system and its controls
c. Any other mechanical systems or controls

G. Software

Laparoscopes and hysteroscopes that include software are either minor or moderate concern devices, depending on the design of the particular device. The guidance document "Reviewer Guidance for Computer Controlled Medical Devices" discusses ODE's general requirements for software documentation. You should pay particular attention to the following elements:

1. Description of the software development activities and software quality assurance procedures over the software life cycle.

2. System and software requirements and design. This should include: hardware requirements, programming language and program size, and software functional requirements. Traceability between safety requirements and hazards should be clearly indicated.

3. Structure chart depicting the partition of the system into functional units.

4. Description of the verification and validation activities at unit, integration, and system level, including pass/fail criteria, and the system level functional test plan. Traceability between hazards, safety functions, and testing should be demonstrated.

5. Summary of the verification and validation test results *in sufficient detail to demonstrate that software requirements were met* at various levels of testing, and the results of system level testing.

6. Current software version number and date, as well as a list of any remaining bugs or errors.

H Sterilization

1. Background

Hysteroscopes and laparoscopes that are intended to contact or enter sterile tissue are considered critical devices and, therefore, require sterilization before use.

2. Required Information

Provide detailed instructions for reprocessing (cleaning and sterilizing) the device, including instructions necessary for any assembly/disassembly. Also, include a warning that the device should be thoroughly cleaned and sterilized according to validated infection control procedures before use/reuse.

a. The cleaning instructions should describe careful, manual cleaning and rinsing of both the hysteroscope/laparoscope's exterior surface and interior channels using a brush and detergent/ enzymatic solution to dissolve and loosen proteinaceous materials immediately after use. (Flexible hysteroscopes/laparoscopes require cleaning of the suction/biopsy channel in the insertion tube, umbilical cord and control head while rigid instruments require careful cleaning of the external surface and any internal channels.) The cleaning instructions should identify compatible cleaning solutions by generic names (e.g., enzymatic cleaning solutions, protein binding agents, etc.) and any areas of the device that are particularly difficult to clean, as well as any specified methods and necessary accessories (e.g., brushes).

b. The rinsing instructions should include purging of all internal channels (if applicable) alternately with air and water.

c. Leak testing before immersion of the control head of flexible hysteroscopes/laparoscopes should be described. This may be either a dry test using a pressure gauge or a wet test that relies on evidence of air bubbles when the inflated portion is submerged in water.

d. Any liquid steriliants used must be identified and cleared by FDA. General reference to a class of germicides, e.g., 2% glutaraldehyde, is currently acceptable. Instructions should recommend that the entire endoscope be exposed to the liquid chemical germicide according to the labeling of the germicide (appropriate time and

temperature). Liquid sterilization may be manual or automated, and, if automated, instructions must identify suitable adapters for all interior channels of the hysteroscope/laparoscope.

e. Thorough post process drying instructions should be recommended, as needed, in order to reduce recontamination before reuse. Instructions should include a step where air is forced through all channels following either manual or automated reprocessing to remove residual rinse water.

f. Specify at least one validated method for sterilization and identify the specific parameters (e.g., cycle parameters, aeration, specific liquid chemical germicide, loading of sterilizer, etc.) which should be used. If the labeling lists a generic type of sterilization process with no specifics on cycle parameters, then the applicant must validate all forms of the listed generic process, e.g., "steam sterilization."

g. Provide information to help the user identify any circumstances or conditions when the device may be adversely affected by reprocessing. This information should address the material compatibility with the immersion fluid.

h. Provide a certification regarding validation of the reprocessing instructions signed by the applicant, its agent, or other legally responsible individual.

For important additional information on reprocessing, please refer to the draft "Labeling Reusable Medical Devices Reprocessing in Health Care Facilities: FDA Reviewer Guidance" (March 1995). A copy of this guidance may be obtained from DSMA.

I. Labeling

A. Hysteroscopes

Indications for Use

Note: Hysteroscopes are used as tools for access to the uterine cavity and are not, in and of themselves, a method of surgery.

Diagnostic Hysteroscopy

- Abnormal Uterine Bleeding

- Infertility & Pregnancy Wastage
- Evaluation of Abnormal Hysterosalpingogram
- Intrauterine Foreign Body
- Amenorrhea
- Pelvic Pain

Operative Hysteroscopy

- Directed Biopsy
- Removal of Submucous Fibroids and Large Polyps
- Submucous Myomectomy
- Transection of Intrauterine Adhesions
- Transection of Intrauterine Septa
- Endometrial Ablation

You may wish to modify this list of indications, particularly for narrow-gauge hysteroscopes intended to be used in an office setting. The choice of location for hysteroscopy (i.e., office setting vs. hospital) may be altered by medical disease, cervical stenosis, and pelvic infection.

Contraindications for use

- acute pelvic inflammatory disease

Hysteroscopy may be contraindicated by the following conditions, depending on their severity or extent:

- inability to distend the uterus
- cervical stenosis
- cervical/vaginal infection
- uterine bleeding or menses
- known pregnancy
- invasive carcinoma of the cervix
- recent uterine perforation
- medical contraindication or intolerance to anesthesia.

Contraindications to Endometrial Ablation
Hysteroscopic endometrial ablation, whether by laser or electrosurgery, should not be undertaken without adequate training, preceptorship, and clinical experience. Additionally, endometrial biopsy should be performed prior to any ablation. The following are clinical conditions that can significantly complicate hysteroscopic endometrial ablation:

- Adenomatous Endometrial Hyperplasia
- Uterine Leiomyoma

- Severe Adenomyosis
- Pelvic Pain (Subtle PID)
- Uterine anomalies

Contraindications to Hysteroscopic Myomectomy

Hysteroscopic myomectomy should not be undertaken without adequate training, preceptorship, and clinical experience. The following are clinical conditions that can significantly complicate hysteroscopic myomectomy:

- Severe anemia
- Inability to circumnavigate a myoma due to myoma size. (e.g., predominantly intramural myomas with small submucous components).

Warnings

- For use only by physicians trained in hysteroscopy.
- Suspicion of pregnancy should suggest a pregnancy test before the performance of diagnostic hysteroscopy.

<u>For Continuous Flow Hysteroscopy:</u>

If a liquid distention medium is used, strict fluid intake and output surveillance should be maintained. Intrauterine instillation exceeding 1 liter should be followed with great care to the possibility of fluid overload.

Potential Complications of Continuous Flow Hysteroscopy:

- Hyponatremia
- Hypothermia
- Uterine perforation resulting in possible injury to bowel, bladder, major blood vessels, and ureter.
- Pulmonary edema
- Cerebral edema

Precautions

- Vaginal ultrasonography before hysteroscopy may identify clinical conditions that will alter patient management.

- Intrauterine distension can usually be accomplished with pressures in the range of 35-75 mmHg. Unless the systemic blood pressure is excessive, it is seldom necessary to use pressures greater than 75-80 mmHg.

Instructions for Use

- Clinical Use
- Directions for use, including identification of compatible light sources and cables
- Assembly, disassembly, care & storage
- Cleaning and Sterilization

B. Laparoscopes

Indications for Use (Gynecologic Surgery)

Note: Laparoscopes are used as tools for access to the abdomen and are not, in and of themselves, a method of surgery.

- Unexplained pelvic pain (acute, chronic)
- Infertility Work-up
- Tubal sterilization
- Diagnosis and/or treatment of ectopic pregnancy
- Evaluation, diagnosis and/or treatment of pelvic tumors, including myomata (less than 16 weeks gestational size)
- Evaluation of congenital anomalies of the pelvic organs
- Retrieval of foreign bodies
- Determination of the presence and extent of pelvic endometriosis
- Determination of the presence and extent of pelvic inflammatory disease (if not in acute stage)
- Access to abdomen for surgical procedures such as LAVH
- Visualization, diagnosis and/or treatment of perforate abdominal (pelvic) organs

You may wish to modify this list based on the particular characteristics of your laparoscope, particularly for narrow-gauge laparoscopes intended to be used in an office setting. For a more exhaustive list of indications and contraindications for gynecologic laparoscopy, refer to the *Manual of Endoscopy*, prepared by the American Association of Gynecologic

Laparoscopists (AAGL), as well as other credentialed sources

Contraindications for Use

Laparoscopy may be contraindicated by pregnancy greater than 16 weeks gestation or abdominal mass of comparable size.

Laparoscopy may also be contraindicated by the following conditions, depending on their severity or extent:

- Class IV cardiac decompensation
- Bowel obstruction
- Ileus
- Cardiac disease
- Intraperitoneal hemorrhage
- Diaphragmatic hernia
- Infection with acute peritonitis
- Previous abdominal surgery
- Obesity
- Thin nulliparous patient
- Chronic obstructive lung disease
- Liver failure with established collateral vessels

Warnings

- For use only by clinicians trained in laparoscopy.

Precautions

- Ultrasonography before laparoscopy may identify clinical conditions that will alter patient management.

- Abdominal puncture sites 7 mm or greater (for the introduction of auxiliary instrumentation) may be a source of herniation.

- Lasers and electrosurgical probes should not be activated simultaneously. Further, when one is activated, the tip of the other should be completely retracted. This avoids deflection of the energy to the other tip.

- The abdomen can be adequately distended by pressure in the range of 15-20 mmHg. It is seldom necessary to use an abdominal pressure greater than 20 mmHg.

- During unipolar electrosurgery, inadvertent burns can occur when the appropriate patient return path is obstructed or as a result of capacitive coupling. An important maxim:

  Avoid combinations of devices made of both conducting and insulating materials, especially metal trocars with nonconductive trocar anchors, screws, etc. That is: "Use like with like."

Instructions for Use

- Clinical Use
- Directions for use, including identification of compatible light sources and cables.
- Assembly, disassembly, evaluation, care & storage
- Cleaning and Sterilization

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SE COMPARISON CHART

A. SIMPLE RIGID ROD LENS

510(K) NUMBER _____
DEVICE NAME _____

DEVICE DESCRIPTION	YES	NO
1. SYSTEM BLOCK DIAGRAM	_	_
2. SCHEMATICS, DIAGRAMS	_	_
3. MATERIALS (Scope, lens, fibers)	_	_
Biocompatibility Test present? (If new material)	_	_

SAFETY REQUIREMENTS

(Fill out information)

1. THERMAL SAFETY (IEC 601-2-18, Draft)

Scope's exterior surface maximum temperature(^{o}C) _____^{o}C (Specify location(s))

Time duration when the maximum temperature is reached _____hrs
(Recommend minimum of 2 hours)

2. ELECTRICAL SAFETY (IEC 601-2-18, Draft)

Leakage current from the eyepiece of laparoscope when electrosurgical devices are used _____mA
(Recommend not to exceed 50 mA)

COMPONENTS

	Proposed device	**Predicate device**
1. SCOPE		
Working length	_____	_____
Outer diameter	_____	_____
Channel diameter (If applicable)	_____	_____

	Proposed device	Predicate device
2. LIGHT SOURCE		
Recommended type of source (e.g. Quartz, Xenon)		
Power rating of source (watts)		

OPTICAL COMPONENTS

A. OBJECTIVE LENS

Focal length (mm)		
Field of view (degree)		
Direction of view (degree)		

B. ILLUMINATION FIBERS

Ratio of luminous energy transmitted to energy delivered		

C. EYEPIECE (If applicable)

Power of eyepiece (Magnification)		

D. WHOLE SYSTEM (Image quality)

Resolution:		

This information can be provided using various methodologies:
e.g., USAF bar pattern (line pairs/mm), or
signal-to-noise ratio versus frequency (db), or
modulation transfer function (MTF).

Distortion:		

For example, this could be provided by imaging a piece of graph paper and providing a comparison of the paper and the photographed image of the graph paper. If the distortion is corrected by signal processing, provide the resulting, corrected image of the graph paper.

B. FIBEROPTIC & ELECTRONIC IMAGING SYSTEMS

510(K) NUMBER _____

DEVICE NAME _____

DEVICE DESCRIPTION	PRESENT YES	NO
1. SYSTEM BLOCK DIAGRAM	_	_
2. SCHEMATICS, DIAGRAMS	_	_
3. MATERIALS (Scope, lens, fibers)	_	_
Biocompatibility Test present? (If new material)	_	_

SAFETY REQUIREMENTS	(Fill out information)
1. ELECTRICAL SAFETY (IEC 601-1 or UL 544) **	
** *Applicable if the system has a video component*	
Enclosure leakage current (mA)	_____ mA
Patient leakage current (mA)	_____ mA
ELECTRICAL SAFETY (IEC 601-2-18, Draft)	
Leakage current from the eyepiece of laparoscope when electrosurgical devices are used (Recommend not to exceed 50 mA)	_____ mA
2. ELECTROMAGNETIC COMPATIBILITY (IEC 601-1-2)	
Certification that the device complies with acceptable standards for Immunity and Emissions (i.e., CISPR 11, IEC 601-1-2), or test results which guarantee a similar level of protection, or a justification of why this information is unnecessary (e.g., due to device design or working conditions).	
3. THERMAL SAFETY (IEC 601-2-18, Draft)	
Scope's exterior surface maximum temperature(^{o}C) (Specify location(s))	_____ ^{o}C
Time duration when the maximum temperature is reached (Recommend minimum of 2 hours)	_____ hrs

COMPONENTS

(Fill out information)

	Proposed device	**Predicate device**
1. SCOPE		
Working length		
Outer diameter		
Channel diameter (If applicable)		
2. VIDEO CAMERA (If applicable)		
Number of pixels or lines - Horizontal		
Number of pixels of lines - Vertical		
Number of pixels used for color		
3. VIDEO MONITOR (If applicable)		
Number of lines - Horizontal		
Number of lines - Vertical		
4. LIGHT SOURCE		
Type of source (e.g., Quartz, Xenon)		
Power rating of source (watts)		
6. WHOLE SYSTEM (Image quality)		
Resolution:		

This information can be provided using various methodologies:
e.g., USAF bar pattern (line pairs/mm), or
signal-to-noise ratio versus frequency (db), or
modulation transfer function (MTF).

Distortion: _____ _____

For example, this could be provided by imaging a piece of graph paper and providing a comparison of the paper and the photographed image of the graph paper. If the distortion is corrected by signal processing, provide the resulting, corrected image of the graph paper.

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OPTICAL COMPONENTS

	Proposed device	**Predicate device**
A. OBJECTIVE LENS		
Focal length (mm)		
Field of view (degree)		
Direction of view (degree)		
B. ILLUMINATION FIBERS		
Ratio of luminous energy transmitted to energy delivered		
C. IMAGING TRANSMISSION SYSTEM (Fiberoptic or Electronic)		
FIBEROPTIC IMAGING TRANSMISSION		
Total number of fibers		
Fibers per square millimeter		
Size of fiber core (mm)		
Area of active fiber per square millimeter		
Ratio of luminous energy transmitted to energy delivered		
ELECTRONIC IMAGING TRANSMISSION		
Total number of pixels		
Pixels per square millimeter		
Size of pixel (micron)		
Active area of CCD imager (mm x mm)		
D. EYEPIECE (If applicable)		
Power of eyepiece (Magnification)		
E. COUPLING LENS (If applicable)		
Focal length (mm)		
Focal number		

SOFTWARE DOCUMENTATION (If applicable)

	PRESENT	
	YES	NO
Design	_	_
Development	_	_
Testing	_	_
Results	_	_
Verification/Validation	_	_
Hazard Analysis	_	_

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Laparoscopic and Hysteroscopic Accessories
List of Exempt Devices

(From Federal Register Notice 1124, January 16, 1996)

Effective February 16, 1996, the following laparoscopic and hysteroscopic accessories are exempt from the 510(k) premarket notification procedures, **if** they are not part of a specialized instrument or device delivery system, **and** if they do not have adaptors, connectors, channels, or other portals for electrosurgical, laser, or other power sources.

lens cleaning brush
biopsy brush
clip applier (without clips)
cannula (without trocar or valves)
ligature carrier/needle holder
clamp/hemostat/grasper
curette
instrument guide
ligature passing and knotting instrument
suture needle (without suture)
retractor
mechanical (non-inflatable) snare
stylet
forceps
dissector
scissors
suction/irrigation probe

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