Our forward-thinking, minimalist-designed modular digital hysteroscope currently in development offers significant benefits for the doctor, patient, and healthcare institution.

GyneVue is being uniquely developed to:

1. Simplify equipment acquisition, usage, and maintenance regardless of the hysteroscopic procedure site of care:
   - The design of our hysteroscope is an integrated, compact system requiring minimal parts: Control handle, modular shafts, small information storage device, and a monitor (e.g., basic monitor, tablet, laptop, cell phone, etc.).
   - The overall setup is simple, fast, and requires minimal space. And since there are few components to attend to, maintenance and reprocessing will be significantly reduced.
   - We will be complementing the hysteroscope with a turn-key procedure kit, complete with all of the equipment necessary in performing a successful diagnostic or therapeutic hysteroscopy. We are developing this so that valuable time, devoted to purchasing and accounting for accessory equipment from multiple vendors, will be essentially eliminated.

2. Match the Hysteroscope and Procedure to Female Patient Anatomy

Since female anatomy varies among women and requires specific instrumentation to perform a successful intervention, we are designing GyneVue with a host of complex benefits in mind. We are keeping in mind that the intended hysteroscopic procedure will affect the management of that patient and what preparations/precautions must be taken to ensure a successful outcome, including these significant anatomical differences encountered prior to a diagnostic or therapeutic procedure:
The design of our scope will suitably address these issues

GyneVue is being developed as the first fully anatomically compliant hysteroscope.

- GyneVue is a modular system consisting of three procedure-specific reusable shafts.
  - For diagnostic procedures, we are developing a rigid shaft with a diameter of 3mm, optimal for the majority of nulliparous (patient with no vaginal births) and post-menopausal women who typically have a narrow or stenotic cervix and the need for dilation (an uncomfortable added step in performing a hysteroscopy) is minimized. The working length is 22cm, sufficient to cover virtually any body type.
  - For therapeutic procedures, a 4.5mm-diametered rigid, continuous flow operative shaft design will be ideal for accommodating industry standard 5Fr. hand instruments and again, maintaining a small diameter to minimize the need for cervical dilation. The working length is 22cm.
  - Since traditional hysteroscopes typically have a 30° direction of view, visualizing the entire uterine cavity can be accomplished by simply rotating the hysteroscope which typically minimizes scope manipulation. This is especially critical when performing a hysteroscopy on an awake patient. However, with a 30° direction of view, the scope must be introduced through the cervix with an off-center visualization of the cervix to avoid traumatizing the surrounding cervical tissue and minimizing an awake patient’s potential discomfort. Since our digital system has a 0° direction of view, insertion through the cervix is straight forward.

An additional feature in the diagnostic and operative shafts is that their tips will have the ability to ‘pivot’ up to 45° laterally left and right (with instrument introduction through the operative shaft, pivoting range will be
up to 30°). This allows for complete uterine surveillance while minimizing any scope manipulation and allows close inspection or therapy of the tubal ostia and fallopian tube cannulation.

- The third shaft is a rigid operative shaft precisely designed for tissue removal/morcellation procedures. It is 5.5mm in diameter and has an 18cm working length with a 3mm straight operative channel allowing for use with virtually all tissue removal/morcellation manual or automated systems.

- The reusable control handle is being developed to be user-friendly with a simple tip angulation controllable wheel and three feature buttons offering picture capture, video recording, and lighting control.

- Since this is a digital scope that has a fixed-focused depth of field, automatic exposure feature, and integrated LED illumination, there is no need for a camera head/adapter assembly, focus adjustment, or add-on light cable (which could potentially interfere with scope manipulation).

- In combination with a uniquely designed reusable handle, the overall design creates a very user-friendly and lightweight package and therefore, in combination with the minimalist component design, provides for optimal procedural efficiency.

3. Require Minimum Physician Training

- The unique design of the GyneVue modular digital hysteroscope provides the user with a simple setup, minimal components, and user-friendly features that will minimize physician training and scope usage for both diagnostic and therapeutic procedures.

Additionally, we are developing a training program that:

- Utilizes current studies and printed reference materials

- Develops new materials on the use of proper techniques

- Works with society’s to develop guides describing product functions and usage, as well as interactive video and PowerPoint presentations

- Utilizes leadership for mentoring
• Creates internal, highly qualified Tech Support to handle FAQ’s and equipment emergencies

• Regularly publishes and updates and helpful information

4. Provide a Convenient ‘One-Stop’ for Hospital, Outpatient, and In-Office Hysteroscopic Procedures

• In our hysteroscopic system, there are few components to connect and by supplying the required accessories and disposables, very little preparation is required. Due to our intuitive and simple design, operation of the equipment both enhances efficiency and reduces potential errors or downtime during the procedure. The ‘minimalist’ approach to this design of the equipment further ensures that repairs, maintenance, and reprocessing are minimized.

• The EndoVentions Medical GyneVue hystroscope, and its complementary accessories offers the following benefits:
  
  o Minimizing equipment acquisition, repairs/maintenance, and reprocessing costs.
  
  o Improving efficiency of a GYN practice through minimal components, user-friendly design, and anatomically specific configurations.
  
  o Designing products perfectly suited for a small surgical space setting (i.e., office practice).
  
  o Creating products equally useful in both awake patients and patients under general anestheisa (i.e., OR and outpatient environments).

5. Offer a Low Per Procedure Cost Solution

• Delivering high quality healthcare typically is an expensive proposition. The GyneVue Hysteroscopic design ensures that performing ALL hysteroscopic procedures will minimize the impact to the healthcare providers budget in the following ways:

• All the equipment is reusable.

• The GyneVue platform is compact and only consists of a small number of components.
• Ongoing maintenance and repairs are significantly less than traditional hysteroscopic setups as a result of the integrated and robust design of all components as well as the limited number of components that makeup the system.

• Acquisition cost of the GyneVue components is less than traditional hysteroscopic rod lens and video equipment systems.

• We are in the process of developing a novel purchasing program that simplifies the purchasing process, allows for immediate purchase of the equipment, and minimizes the monthly burden to healthcare budgets. In addition, there will be special upgrade option that allows immediate equipment substitution to the latest designs of hardware and/or software at minimal-to-no cost to the healthcare provider.

**Summary Specific Points:**

• A major objective in the development of the GyneVue hysteroscope is to minimize the size and quantity of complementary equipment (e.g. light sources, light cables, camera boxes, and camera heads, etc.) currently required to deliver a functioning video hysteroscopic system thereby reducing expensive surgical space requirements, high acquisition costs, and ongoing maintenance costs.

• We are engineering our hysteroscope to be modular: a reusable control handle mated to three interchangeable shafts - one for diagnostic procedures, one for operative procedures, and one for tissue removal/morcellation.

• The shaft is being optimized in functionality and in size to ensure successful application in virtually all female anatomical variations and all surgical site settings. This is especially critical as more and more hysteroscopic procedures move to procedural settings where the patient is awake during the procedure.

• Our hysteroscope is being developed to become more user-friendly over current technology and will require only minimal training to operate. This includes a universal handle that mates to procedure-specific modular shafts, each specifically sized and designed to minimize discomfort to the patient, lessen the need for cervical dilation, and optimize ease of introduction.

• Simple ‘plug and play’ configuration easily connects directly to any monitor/display; no need for a full video tower setup.

• Capable of actively pivoting the tip of the scope up to 30–45° in two bilateral
directions (left/right) yet stiff enough for virtually any introduction technique (especially the vaginoscopy approach).

- High quality, bright, and stable imaging
- Capable of picture capturing and video recording

**Marc Levinson Background:**

Marc A. Levinson is a senior executive with extensive experience in the invention and marketing of minimally invasive surgical devices, especially in all scope designs (i.e., fiberoptic, rod lens, and digital). He has made significant contributions to the success of both large and small medical device companies Richard Wolf Medical, Olympus, and Karl Storz Endoscopy, as well as startup ventures. Part of his passion is to create compelling devices and simplifying delivery of healthcare, as well as promoting training and educational programs for clinicians and associated healthcare professionals.

See more at [www.gynevue.com](http://www.gynevue.com)

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