

A RECOMMENDATION REPORT

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Table	e of Contents	
1.	EXECUTIVE SUMMARY	2
2.	IN-OFFICE HYSTEROSCOPY VERSUS HOSPITAL BASED HYSTEROSCOPY	3
3.	OPERATIVE HYSTEROSCOPY IN THE OFFICE SETTING: ENDOMETRIAL ABLATION AND PERMANENT BIRTH CONTROL	6
	3.1 LONG TERM BIRTH CONTROL TECHNIQUES	6
	3.2 ENDOMETRIAL ABLATION PROCEDURES	7
4.	CURRENT PRACTICE DATA	10
	4.1 ADJUSTED PRACTICE DATA	10
5.	IDENTIFICATION AND EVALUATION OF COST CONSIDERATIONS	13
	5.1 INITIAL COSTS	13
	5.2 RECURRING COSTS	15
	5.3 SUMMARY OF COSTS	16
6.	RETURN ON INVESTMENT CALCULATIONS	17
7.	FINAL RECOMMENDATION	19
8.	REFERENCES	21

#### 1. EXECUTIVE SUMMARY

OB & GYN Specialists, P.A., should consider performing operative hysteroscopy surgeries in its offices. Since optimal patient care is the practice's top priority, in-office surgery presents fewer surgical risks to the patient, reduces her out-of-pocket expenses, and provides her a more comfortable surgical setting. The practice currently conducts these surgeries in the hospital, where insurance payouts to the practice are substantially less than if the operations were performed in the office. In the office setting, the practice would increase its revenue stream by performing Essure Tubal Ligations and endometrial ablations.

Many medical supply companies currently market different endometrial ablation surgical methods. Based on the cost required to upgrade OB & GYN Specialists, P.A., facilities and staff to comply with Florida Health Code, the practice should study Boston Scientific's HydroThermAblator® system. This endometrial ablation technique is Level I Surgery, which requires no additional staff or office certification. Thus, the return on investment uses costs associated with this method for its calculation.

Using projected patient data for 2009, return on investment calculations show that inoffice operative hysteroscopy revenue would completely pay off initial investments and earn a
profit of \$312,284.08. Similarly, in 2010, in-office operative hysteroscopy would net a profit of
\$371,274.58. OB & GYN Specialists, P.A., should invest in in-office operative hysteroscopy
because the procedure would immediately be profitable. More importantly, offering the
procedure in the office as opposed to at the hospital would allow OB & GYN Specialists, P.A.,
to continue to offer its patients top-level care.

#### 2. IN-OFFICE HYSTEROSCOPY VERSUS HOSPITAL BASED HYSTEROSCOPY

Performing operative hysteroscopy procedures in an office setting as opposed to a hospital setting offers many benefits to both the patient and the doctor. This section will address these benefits to prove why OB & GYN Specialists, P.A., should study whether it is cost-advantageous to its practice to perform operative hysteroscopy procedures in its three Orlando-area offices rather than at Winnie Palmer Hospital as it currently does.

#### Patient Benefits

Patients prefer in-office surgeries because it reduces insurance costs, limits anesthesia risks, decreases the return-to-work time and offers more convenience. Table 2.1 shows these patient benefits of in-office operative hysteroscopy. A discussion follows.

Table 2.1 Patient Benefits of In-Office Operative Hysteroscopy vs. at Hospital					
Consideration Hospital In-Office					
Insurance Deductible	\$1,000-\$2,000	\$5-\$50			
Anesthesia	General	Paracervical Block			
Return-To-Work Time	Few Days	Same Day			
Convenience	No	Yes			

Currently, OB & GYN Specialists, P.A., performs operative hysteroscopy procedures at Winnie Palmer Hospital. Hospitalization for hysteroscopy procedures involves a greater burden to the patient than it would to undergo these procedures as an outpatient at an OB & GYN Specialists, P.A., office.

Foremost, in-office operative hysteroscopy ability offers the patients a cheaper surgical option. Generally, patients pay insurance deductibles upwards of a few thousand dollars for hysteroscopy procedures that take place in the hospital (Boston Scientific). If these same

procedures took place in an office setting, then the patient would only pay her office co-pay deductible, which ranges from \$5 to \$50 for most insurance plans (Mervis). Financially, patients would prefer in-office operative hysteroscopy.

Medically, in-office operative hysteroscopy is a minimally invasive surgery. Whereas hysteroscopy in the hospital requires general anesthesia, the patient can undergo in-office hysteroscopy with minimal sedation and a paracervical block (Song). Less intense anesthetic limits the concern over complications from general anesthesia. It also means that the patient could return to work on the same day as the procedure (Mervis).

In-office surgery also offers several intangible patient benefits. Hospitals are notoriously slow at patient processing. In-office hysteroscopy would allow the patient to get treated more efficiently and to avoid the hassle and stress of going to the hospital. Similarly, in-office hysteroscopy allows the patient to receive treatment in an already convenient location and comfortable setting, her doctor's office (Boston Scientific).

#### **Doctor Benefits**

Just as the patient benefits greatly from in-office surgeries, so does the doctor. In-office surgery increases insurance reimbursement, generates more patient flow, allows the practice to competitively market itself and improves its infrastructure. Table 2.2 shows the doctor benefits associated with in-office operative hysteroscopy. A discussion follows.

Table 2.2						
Doctor Benefits of In-Office Operative Hysteroscopy vs. at Hospital						
Consideration Hospital In-Office						
Average Reimbursement	\$326.02	\$2,014.80				
Number of Patients	Limited	Increased				
Marketing Differentiation	No	Yes				
Infrastructure Improvement	N/A	Yes				

Doctors have a lucrative financial incentive to perform operative hysteroscopy in an office setting. In 2008, the national average Medicare reimbursement rate for an endometrial ablation hysteroscopy procedure that occurred in a hospital was only \$326.02. If the same procedure took place in an office setting, the reimbursement rate was \$2,014.80 (Boston Scientific). The difference between reimbursement rates is staggering and shows how performing operative hysteroscopy procedures in the office can boost revenue.

Revenue could also rise for several other reasons. First, only one physician at OB & GYN Specialists, P.A., currently performs operative hysteroscopy. If the office had capabilities to perform this procedure in the office, more doctors would learn the procedure's technique, which would translate to more overall procedures (Mervis).

Secondly, offering in-office operative hysteroscopy differentiates OB & GYN

Specialists, P.A., from other local obstetrics and gynecology practices. No practice in the

Orlando area offers in-office operative hysteroscopy, so adding this capability would allow OB

& GYN Specialists, P.A., to market itself as a more convenient and technologically advanced

practice. Patients will consider this capability an important factor when choosing a physician, so

OB & GYN Specialists, P.A., could expect to see an increase in new patients. These new patients

would increase revenue by using additional practice services.

Thirdly, adding the capability to perform in-office operative hysteroscopy positions OB & GYN Specialists, P.A., for the future. As new technologies and procedures develop within the field of operative hysteroscopy, OB & GYN Specialists, P.A., would already have the technology infrastructure to add services to its practice.

## 3. OPERATIVE HYSTEROSCOPY IN THE OFFICE SETTING: ENDOMETRIAL ABLATION AND PERMANENT BIRTH CONTROL

Most hysteroscopy surgeries now occur as outpatient procedures. However, since the patient must usually undergo general anesthesia, these surgeries occur in hospital settings.

Recent advances in operative hysteroscopy technique and equipment have minimized the need for general anesthesia. In fact, many operative hysteroscopy procedures can now take place under local anesthetic, which effectively eliminates the need for patient hospitalization (Nikolau, Salman, & Richardson, 2008). Furthermore, independent studies have all concluded that doctors can perform operative hysteroscopy safely and effectively in office settings (Lindheim, Kavic, Shulman, & Sauer, 2000).

OB & GYN Specialists, P.A., currently performs two types of operative hysteroscopy procedures in the hospital: long term birth control and endometrial ablation. The following subsections discuss these procedures

#### 3.1 LONG TERM BIRTH CONTROL TECHNIQUES

Long term birth control offers a more effective and longer lasting form of preventing pregnancies than do pharmaceutical or physical contraceptives. OB & GYN Specialists, P.A., currently performs three different types of long term birth control. These techniques are intrauterine devices, tubal ligation, and Essure®. Investing in operative hysteroscopy equipment would allow the practice to perform more Essure® procedures. This report will discuss this implication further in Sections 4 and 5. A description of these three types of long term birth control follows.

Intrauterine Devices

Intrauterine Devices (IUD) prevent unwanted pregnancies by changing the conformation and internal chemical environment of the uterus. IUDs thicken the cervical mucus, prevent release of the egg during ovulation and hinder the movement of sperm during intercourse. A doctor inserts an IUD into the upper part of the vagina. IUDs last between five and ten years, after which a doctor must remove and replace it (Planned Parenthood). Doctors insert the IUD by feel and do not use any hysteroscopy equipment (Mervis).

#### Tubal Ligation

Tubal ligation is a form of permanent birth control. A doctor uses laparoscopic equipment to seal the fallopian tubes. With the fallopian tubes closed, an egg cannot reach the uterus during ovulation. If there is no egg in the uterus, no fertilization will occur during intercourse. This form of contraceptive is electively reversible, but is otherwise permanent. Doctors do not use hysteroscopy equipment with this form of long term birth control (Mervis).

#### Conceptus: Essure

Conceptus received FDA approval for its Essure product in 2002. Essure is a less intrusive form of permanent birth control than tubal ligation. A doctor inserts the Essure device into the fallopian tubes using hysteroscopy equipment. The fallopian tubes then grow new tissue around the insert, which effectively fuses the tubes shut, preventing fertilization. Essure is permanent and not reversible (Conceptus).

#### 3.2 ENDOMETRIAL ABLATION PROCEDURES

Endometrial ablation is a surgical technique designed to treat menometrorrhagia by removing the endometrial tissue. Four medical supply companies offer comprehensive solutions to perform endometrial ablation in office: Boston Scientific, ETHICON, American Medical Systems, and Hologic. Each company's product reduces excessive menstrual bleeding through

slightly different methods. Since complying with Florida Health Code for performing in-office surgeries will present a major cost consideration (discussed more in Section 5), the current section introduces these four endometrial ablation techniques. This report does not include detailed descriptions of the procedures since medical supply companies provide training in specific endometrial ablation techniques.

Boston Scientific: HydroThermAblator® System

Boston Scientific introduced the HydroThermAblator® (HTA) System in 2001 after it received FDA approval (Song). This technique sedates patients with a paracervical block, then introduces a heated saline solution into the uterine cavity. As the heated saline circulates across the uterine walls, it burns the lining of the uterus. Hysteroscopy video equipment allows the doctor to directly watch the endometrial lining change from a red color to white during the surgery (Carter).

ETHICON: THERMACHOICE®

Owned by Johnson & Johnson, ETHICON introduced its THERMACHOICE® system in 2000. It utilizes the uterine balloon technique to reduce abnormal uterine bleeding. With this technique, the doctor inserts a deflated balloon into the uterus. The doctor then inflates the balloon with a sterile fluid. After inflation, the doctor heats the fluid, which heats the balloon lining, which in turn burns the endometrial tissue (ETHICON). The doctor does not use hysteroscopy video equipment during the procedure, but does use it to diagnosis the condition of the endometrial tissue before and after. (Carter).

American Medical Systems: Her Option®

American Medical Systems introduced Her Option® in 2001. This technique utilizes cryoablation to treat the uterine lining. Unlike the previous two systems which use heated fluids

8

to treat the endometrial lining, this system uses a probe to introduce freezing liquid nitrogen to

perform ablation. In this technique, the doctor uses ultrasound to visualize where the probe is

situated in the uterus (American Medical Systems). He or she does not use hysteroscopy video

equipment during the procedure, but does use it to diagnosis the condition of the endometrial

tissue before and after.

Hologic: NovaSure®

Hologic's NovaSure® received FDA approval in 2001. This technique uses bipolar

radiofrequency—that is, electromagnetic waves—to remove the endometrium. The doctor first

dilates the cervix, inserts a triangular mesh into the uterine cavity and then pulses radio waves

through the mesh. This energy pulls the endometrial lining to the mesh, which is removed after

the procedure is completed. The doctor uses ultrasound to align the mesh in the uterus.

(Hologic). He or she does not use hysteroscopy video equipment during the procedure, but does

use it to diagnosis the condition of the endometrial tissue before and after.

#### 4. CURRENT PRACTICE DATA

Due to a change in billing systems, comprehensive billings records and case histories for OB & GYN Specialists, P.A., are only available for the 2007 fiscal year and for the 2008 fiscal year through November 11, 2008. Table 4.1 shows the number of long term birth control and hysteroscopy cases for these two years and the projected data for 2008, 2009 and 2010. It also shows the adjusted 2009 and 2010 practice data as projected if the practice offered in-office operative hysteroscopy.

	Table 4.1OB & GYN Specialists, P.A., Projected Case Data						
	Number of Cases						
Type of Diagnosis	2007	2008 (to 11/11/08)	Projected 2008 <sup>1</sup>	Projected 2009 <sup>2</sup>	Projected 2010 <sup>3</sup>	Adjusted 2009	Adjusted 2010
Diagnostic Diagnostic	2007	11/11/00)	2000	2009	2010	2007	2010
Hysteroscopy	7	7	8	8	8	8	8
Diagnostic							
Hysteroscopy with							
Biopsy	48	51	59	54	56	54	56
Essure Tubal							
Ligation	7	7	8	8	8	52	67
Laparoscopic Tubal							
Ligation	36	24	28	32	30	11	7
Endometrial							
Ablation	165	124	144	155	149	228	261
<b>IUD Insertions &gt; age</b>							
40	62	58	67	65	66	55	52
<b>IUD Insertions &lt; age</b>							
40	232	291	337	285	311	270	288
Menometrorrhagia							
> age 40	486	432	500	493	497	493	497

#### 4.1 ADJUSTED PRACTICE DATA

The projected number of cases in 2009 and 2010 does not account for the potential increased number of patients electing to undergo Essure tubal ligation procedures or surgical solutions to menometrorrhagia. In-office operative hysteroscopy offers many advantages to

<sup>&</sup>lt;sup>1</sup>Projected 2008 data estimated by computing average number of cases per month through November 11, 2008, and extending this through a 12-month year.

<sup>2</sup> Projected 2009 data estimated by averaging 2007 and Projected 2008 data.

<sup>&</sup>lt;sup>3</sup> Projected 2010 data estimated by averaging Projected 2008 and Projected 2009 data.

hospital procedures as discussed in Section 2. As such, it is likely that the number of endometrial ablation procedures and Essure tubal ligations would increase if OB & GYN Specialists, P.A., offered in-office hysteroscopy (Mervis). To accurately calculate the return on investment in Section 6, this data should be adjusted.

In terms of long term birth control, OB & GYN Specialists, P.A., performs IUD insertions more often than any other technique because the procedure is both temporary and non-invasive as compared to the highly invasive laparoscopic tubal ligation. Dr. Mervis suggests that a small number of patients currently electing to have IUDs inserted would prefer permanent birth control. Permanent birth control desire is more likely in premenopausal women over the age of 40 who do not want to have any more children. Similarly, a small number of women under the age of 40 may also want to have permanent birth control. Conservative estimates place the former category at 15% and the latter at 5% (Mervis). These cases should be added to the projected data for Essure tubal ligation and subtracted from their respective categories.

Likewise, patients electing to pursue permanent birth control through laparoscopic birth control would likely consider Essure tubal ligation as a less invasive alternative. Since laparoscopic tubal ligation is already a permanent birth control method, a relatively higher percentage of these cases would likely prefer in-office Essure insertion. A conservative estimate of this number is 65% (Mervis). These cases should be added to the number of Essure tubal ligations and subtracted from the laparoscopic category.

Offering in-office operative hysteroscopy would also increase the projected number of endometrial ablation procedures. Nonsurgical methods to manage menometrorrhagia include pharmaceuticals and hormone therapy, but these are less effective than endometrial ablation (Carter). Approximately 15% of menometrorrhagia patients could elect to undergo in-office

operative hysteroscopy to treat their condition (Mervis). Again, these cases should be added to the projected number of endometrial ablation cases.

The final two columns of Table 4.1 show the adjusted 2009 and 2010 projections. These numbers will be used to compute the expected return on investment in Section 6 of this recommendation report.

#### 5. IDENTIFICATION AND EVALUATION OF COST CONSIDERATIONS

Adding the capability to perform in-office operative hysteroscopy procedures at OB & GYN Specialists, P.A., presents considerable initial expenditures. Similarly, recurring costs will affect the income generation. To maximize its income and achieve a quicker return on investment, OB & GYN Specialists, P.A., must select an operative hysteroscopy procedure that minimizes its initial investment. This section identifies and evaluates these costs so that Section 6 can present an accurate return on investment calculation. Table 5.1 shows these cost considerations. A discussion follows.

Table 5.1				
In-Office Operative Hysteroscopy Cost Considerations				
Initial Costs	Recurring Costs			
Compliance with Florida Health Code	Procedure Disposables			
Hiring of New Staff	Procedure Anesthetics			
Permanent Video Equipment				
Permanent Hysteroscopy Equipment				

#### **5.1 Initial Costs**

Compliance with Florida Health Code

Renovating existing operating rooms at OB & GYN Specialists, P.A., to comply with Florida Health Code regulating standards of office-based surgeries could present the largest initial cost to the practice. The State of Florida defines three levels of office surgery:

- Level I Surgery—includes minor surgeries under direction of topological or local anesthesia (Franko). The state does not require special certification for Level I Surgeries (Mervis).
- Level II Surgery—defines more complex procedures in which perioperative medication and sedation are used intravenously, intramuscularly, or rectally (Franko). The office

must have special certification and an anesthesiologist on hand to perform Level II Surgeries in the office (Rucki).

Level III Surgery—includes surgeries conducted under general anesthesia (Franko). The
office must have special certification and an anesthesiologist on hand to perform Level
III surgeries in the office (Rucki).

The cost of complying with Florida Health Code for Levels II and III surgeries involves hiring a full time anesthesiologist to the staff at OB & GYN Specialists, P.A. The median annual salary for an anesthesiologist is \$311,073 (Salary.com), so Level II and III compliance presents a significant initial cost. The burden of this salary would negate any financial benefits of performing in-office operative hysteroscopy procedures.

Of the various endometrial ablation procedures outlined in Section 3, only Boston Scientific's HydroThermAblator® (HTA) procedure classifies as Level I Surgery (Rucki). Level I Surgery certification does not require any additional staff members or updating of current operating room standards. Given that all of the endometrial ablation procedures share similar patient success rates (Carter), OB & GYN Specialists, P.A., should only heretofore consider Boston Scientific's procedure for in-office operative hysteroscopy assessment. Adopting the HTA system eliminates compliance with Florida Health Code as an initial cost consideration.

Hiring of New Staff

Hiring new staff also presents a significant potential start-up cost to OB & GYN Specialists, P.A. New staff could include employees to handle billing and scheduling issues, to provide medical assistance to the physician, to provide facility maintenance or to monitor patient recovery rooms. Average annual salaries for this type of employee range from \$30,000 to \$65,000 (Mervis). Thus, hiring additional employees would also present a substantial start-up

cost. The practice's current support staff, however, could handle the aforementioned administrative issues. Thus, hiring new staff will not present an initial investment to OB & GYN Specialists, P.A.

Permanent Video Equipment

Performing operative hysteroscopy requires high resolution video equipment (Nikolau, Salman and Richardson). This equipment includes a digital video camera, a light source, scopes, diagnostic sheathes, graspers, storage trays, and monitors. These considerations would cost approximately \$18,000 (Rucki). Investment in this technology would slow the rate of return for the practice.

To avoid this cost, OB & GYN Specialists, P.A., should also perform Essure tubal ligation procedures as described in Section 3. If the practice performs at least two Essure tubal ligations a month, then Conceptus will purchase the video equipment for the practice (Rucki). The adjusted projections of Essure Tubal Ligations through 2010 (Section 4) predict that the practice will perform at least two of these procedures a month. As such, the cost of video equipment will not present an initial investment to the practice.

Permanent Hysteroscopy Equipment

As discussed above, the practice should consider Boston Scientific's surgical solution. Purchasing Boston Scientific's HydroThermAblator® system will cost OB & GYN Specialists, P.A., \$1,050 as a one-time investment (Rucki).

#### 5.2 RECURRING COSTS

Procedure Disposables

Disposables for Boston Scientific's HTA system cost \$995 per surgery (Rucki). The practice will incur this cost every time it performs an endometrial ablation. Similarly,

disposables for Conceptus' Essure Tubal Ligation cost \$282 per procedure (Hopkins, Creedon and Wagie). The practice will also incur this cost every time it performs an Essure Tubal Ligation.

#### Procedure Anesthetics

The practice would incur recurring costs for general anesthetics, paracervical blocks and post-operative sedation pharmaceuticals every time it performs a surgery. These services and supplies average \$150 per surgery (Rucki).

#### **5.3 SUMMARY OF COSTS**

The return on investment presentation in Section 6 considers the initial and recurring costs discussed in this section. Table 5.2 summarizes the specific cost considerations and cost frequencies discussed in this section.

		Table 5.2Summary of Cost Considerations  Type of Consideration						
	Compliance with Health Code	Hiring New Staff	Permanent Video Equipment	Permanent Hysteroscopy Equipment	HTA Disposables	Essure Disposables	Procedure Anesthetics	
Cost	N/A	N/A	N/A	\$1,050	\$995	\$282	\$150	
Frequen	cy N/A	N/A	N/A	One-Time	Per Surgery	Per Surgery	Per Surgery	

#### 6. RETURN ON INVESTMENT CALCULATIONS

This report now considers the economic feasibility of OB & GYN Specialists, P.A., to add operative hysteroscopy to its in-office surgery repertoire. Based on the projected patient data of Section 4 and the cost considerations detailed in Section 5, this section will show the theoretical rate of return on investment for the practice. Whether the practice can recoup its initial investment costs in a realistic amount of time will determine the final recommendation presented in Section 7.

Table 6.1 shows the return on investment if OB & GYN Specialists, P.A., adds operative hysteroscopy surgery to its in-office surgical capabilities. This table shows the return on investment for 2009 and 2010 based on adjusted case projections. These calculations assume that the insurance reimbursement rates and procedure disposable costs do not change from their current 2008 values. A discussion follows.

	Table 1Return On Investment Calculation					
		2009	2010			
	Projected Number of Endometrial Ablation Cases	228	261			
Data	Projected Number of Essure Tubal Ligation Cases	52	67			
	HydroThermAblator® Equipment	\$1,050	\$0			
<b>Initial Investments</b>	Hysteroscopy Video Equipment	\$0	\$0			
	HTA Procedure Disposables (per surgery)	\$995.00	\$995.00			
	Essure Disposables (per surgery)	\$282.00	\$282.00			
<b>Recurring Costs</b>	Paracervical Block Anesthetics (per surgery)	\$150.00	\$150.00			
	Endometrial Ablation Reimbursement	\$2,014.80	\$2,014.80			
	<b>Essure Reimbursement</b>	\$2,198.34	\$2,198.34			
Income	Paracervical Block Reimbursement	\$79.00	\$79.00			
	Total Investment	\$1,050	\$0			
	<b>Total Annual Costs</b>	\$283,524.00	\$327,789.00			
	Total Costs	\$284,574.00	\$327,789.00			
	Total Income	\$595,808.08	\$699,063.58			
Return on	Total Profit	\$312,284.08	\$371,274.58			
Investment	% Return on Investment	109.74%	113.27%			

In the same year of investment in in-office operative hysteroscopy capacity, OB & GYN Specialists, P.A., will recoup its initial investment. It will generate \$312,284.04 in profit which translates to a 109.74% return on investment. Since the initial start-up costs incurred in 2009 would already be paid off, the 2010 return on investment is slowed only by annual recurring procedure costs. As such, OB & GYN Specialists, P.A., would generate \$371,274.58 in profit, which translates to a 113.27% return on investment in 2010.

#### 7. FINAL RECOMMENDATION

OB & GYN Specialists, P.A., should practice in-office operative hysteroscopy. The practice will not have to refurbish its current operating rooms or hire new staff to add this capability; it will only have to purchase the appropriate equipment. Projected endometrial ablation and tubal ligation cases in 2009 will completely pay off these initial investment costs for in-office operative hysteroscopy. Adding this capability to OB & GYN Specialists, P.A., is immediately profitable.

Performing endometrial ablation with Boston Scientific's HydroThermAblator® system and tubal ligations with Conceptus' Essure Tubal Ligation system, the practice will generate \$312,284.08 profit in the 2009 fiscal year based on projected patient data. This profit represents a 109.74% return on investment in the first year of in-office operative hysteroscopy. In the second year, OB & GYN Specialists, P.A., will generate \$371,274.58 profit which translates to a 113.27% return on investment.

Additionally, as more doctors in OB & GYN Specialists, P.A., learn how to perform the surgery, these profit margins will increase because more patients will receive treatment. Having the capacity to perform in-office surgeries with this technology will also allow OB & GYN Specialists, P.A., to adapt future operative hysteroscopy procedures to its in-office setting, which limits future cost occurrences.

Adding in-office operative hysteroscopy offers OB & GYN Specialists, P.A., benefits beyond the bottom line. No other obstetrics and gynecology practices in the Orlando area offer this surgery in an office setting, so performing the surgery in-office would differentiate OB & GYN Specialists, P.A., from competing practices.

Most importantly, OB & GYN Specialists, P.A., wants to provide the best care to its patients. In-office operative hysteroscopy cuts the patient's out-of-pocket expenses, reduces her anesthetic risks, allows her to return to work the same day and offers her a more comfortable surgical environment. If OB & GYN Specialists, P.A., adds operative hysteroscopy to its in-office surgical repertoire, then the patients will benefit tremendously.

Based on the considerations presented in throughout this report, OB & GYN Specialists, P.A., should invest in the capability to perform in-office operative hysteroscopy surgeries.

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