

UTAH MEDICAL PRODUCTS INC
Form 10-K
March 12, 2015

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2014

Commission File Number: 001-12575

UTAH MEDICAL PRODUCTS, INC.
(Exact name of registrant as specified in its charter)

Utah 87-0342734
(State or other jurisdiction of incorporation or (I.R.S. Employer Identification No.)
organization)

7043 S 300 W, Midvale Utah 84047
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: Telephone (801) 566-1200
Facsimile (801) 566-7305

Securities registered pursuant to Section 12(b) of the Act:
Title of each class Name of each exchange on which registered
Common Stock, \$.01 Par Value The NASDAQ Global Market
Preferred Stock Purchase Rights

Securities registered pursuant to Section 12(g) of the Act:
(Title of Class)
None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.
Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act.
Yes No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required

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to submit and post such files). Yes No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (Section 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer Accelerated filer Non-accelerated filer Smaller reporting company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes No

State the aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, or the average bid and asked price of such common equity, as of the last business day of the registrant's most recently completed second fiscal quarter. As of June 30, 2014, the aggregate market value of the voting and nonvoting common equity held by nonaffiliates of the registrant was \$171,715,000.

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of the latest practicable date. As of March 11, 2015, common shares outstanding were 3,751,400.

DOCUMENTS INCORPORATED BY REFERENCE. The Company's definitive proxy statement for the Annual Meeting of Shareholders is incorporated by reference into Part III, Item 10, 11, 12, 13 and 14 of this Form 10-K.

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PART I

ITEM 1 – BUSINESS

Currency amounts throughout this report are in thousands except per-share amounts and where noted.

Utah Medical Products, Inc. (“UTMD” or “the Company”) is in the business of producing high quality cost-effective medical devices that are predominantly proprietary, disposable and for hospital use. Success depends on 1) recognizing needs of clinicians and patients, 2) rapidly designing or acquiring economical solutions that gain premarketing regulatory concurrence, 3) reliably producing products that meet those clinical needs, and then 4) selling through

- a) UTMD's own direct channels into markets where the Company enjoys an established reputation and has a critical mass of sales and support resources, or
- b) relationships with other medical companies that have the resources to effectively distribute and support the Company's products.

UTMD's success in providing reliable solutions comes from its proven ability to integrate a number of engineering and technical disciplines in electronics, software, mechanical packaging, instrumentation, plastics processing and materials. The resulting differentiated devices represent significant incremental improvements in patient safety, clinical outcomes and/or total cost over preexisting clinical tools. UTMD's experience is that, in the case of labor-saving devices, the improvement in cost-effectiveness of clinical procedures also leads to an improvement in overall healthcare including lower risk of complications. UTMD markets a broad range of medical devices used in critical care areas, especially the neonatal intensive care unit (NICU), the labor and delivery (L&D) department and the women's health center in hospitals, as well as products sold to outpatient clinics and physician's offices.

The opportunity to apply solutions to recognized needs results from an excellent core of practicing clinicians who introduce ideas to the Company, and key employees who are both clinical applications savvy and development engineering adept.

Domestically, UTMD's products are sold directly to clinical end user facilities by the Company's own direct sales representatives and independent manufacturers' representatives. In addition, some of UTMD's products are sold through specialty distributors, national hospital distribution companies and other medical device manufacturers. Internationally, products are sold directly to end users in the UK, Ireland and Australia, and through other medical device companies and through independent medical products distributors in many other countries. UTMD has representation globally in all major developed countries as well as many underdeveloped countries through several hundred distributors, 135 of which purchased at least five thousand dollars in UTMD medical devices during 2014.

UTMD was formed as a Utah corporation in 1978. UTMD sold stock to the public one time in 1982 for \$1,750 (before offering costs of \$321). Since 1992, UTMD has returned \$113,735 in the form of share repurchases, and an additional \$38,918 in the form of cash dividends, to its public stockholders.

Utah Medical Products Ltd., a wholly-owned subsidiary with manufacturing located in Ireland, was formed in 1995 to better serve UTMD's international customers. In 1997, UTMD purchased Columbia Medical, Inc. (CMI), a Redmond, Oregon company specializing in silicone injection molding, assembly and marketing vacuum-assisted obstetrical delivery systems. In 1998, UTMD acquired the neonatal product line of Gesco International, a subsidiary of Bard Access Systems and C.R. Bard, Inc. In 2004, UTMD acquired Abcorp, Inc., its supplier of fetal monitoring belts. In

2011, UTMD purchased all of the common shares of Femcare Holdings Ltd (Femcare) of the United Kingdom, and its subsidiaries. Femcare is best known for its leading global gyn brand, the Filshie Clip System, a female surgical contraception device (tubal ligation). The addition of Femcare provided product and distribution channel diversification and expansion. Sales of the products, or derivatives of the products, from the four acquisitions noted above, comprised 66% of UTMD's consolidated 2014 sales.

UTMD's corporate headquarters are located at 7043 South 300 West, Midvale, Utah 84047 USA. The corporate office telephone number is 01 (801) 566-1200. Ireland operations are located at Athlone Business and Technology Park, Athlone, County Westmeath, Ireland. The Ireland telephone number is 353 (90) 647-3932. United Kingdom operations are located at Stuart Court, Spursholt Place, Salisbury Road, Romsey, Hampshire SO51 6DJ, UK. The UK phone number is 44 (179) 452-5100. Australia operations are located at Unit 12, 5 Gladstone Road, Castle Hill, NSW 2154, Australia. The Australia phone number is 612 9045 4110.

PRODUCTS

More complete descriptions including part numbers and pictures of UTMD's devices can be conveniently obtained at www.utahmed.com and www.femcare-nikomed.co.uk.

Labor and Delivery/ Obstetrics:

Fetal Monitoring Accessories.

Electronic Fetal Monitoring (EFM) is the standard of care in labor and delivery throughout the modern world. While not all pregnancies are high risk, fetal emergencies can occur suddenly in seemingly normal labors. The use of EFM allows conservation of nursing personnel and has virtually eliminated intrapartum fetal death. Accurate determination of contraction strength increases the safety of labor augmentation and reduces the need for Cesarean section for desultory labor. Infusion of fluid through an intrauterine catheter may cushion the umbilical cord and improve oxygenation of the fetus.

To assist the physician in controlling the effectiveness of administration of oxytocin and monitoring effects of amnioinfusion, contraction intensities, uterine resting tones and peak contraction pressures are closely monitored through the use of an invasive intrauterine pressure catheter system. In addition, to help identify the possible onset of fetal hypoxia, correlation of the changes in fetal heart rate (FHR) relative to the frequency and duration of contractions are often electronically monitored. UTMD's intrauterine pressure (IUP) catheters provide for clinician choices from a traditional fluid-filled system to INTRAN® PLUS, for over twenty years the most widely accepted transducer-tipped system. In addition, adjunct FHR electrodes, leg plates, toco belts and chart paper are provided by UTMD to complete a package of fetal monitoring supplies. UTMD's IUP catheters include:

- IUP-075 and UTMD's other custom fluid-filled clear catheter kits utilize a saline-filled catheter that is placed within the uterine cavity, connected to a separate external reusable or disposable transducer. This product package, utilizing double lumen catheters, was the traditional mode of intrauterine monitoring prior to the introduction of INTRAN. An intrauterine pressure change is transmitted through the fluid column to the external pressure transducer.
- Introduced in 1987, INTRAN was the first disposable intrauterine pressure catheter that placed the pressure transducer at the pressure source within the uterine cavity. This design eliminated the complicated setup of fluid-filled systems and provided more accurate pressure waveforms. INTRAN I was discontinued in 1995 in favor of the more widely preferred INTRAN PLUS, also covered by UTMD's original INTRAN patent.
- INTRAN PLUS was introduced in 1991. The INTRAN PLUS catheter combines the transducer tip concept of INTRAN I with a refined tip design, a zeroing switch that allows the clinician to reset the reference of the monitor, and a dedicated amnio lumen which provides access to the amniotic fluid environment which may be helpful in the diagnosis and intervention of certain fetal conditions. In 1996, a viewport enhancement which allows physicians to observe amniotic fluid in a closed system was added to INTRAN PLUS. In 1997, UTMD introduced several variations to allow user preferences in tip size, zero switch location and amniotic fluid visualization.

UTMD markets tocodynamometer belts, disposable electrodes, catheters and accessories as outlined above, but does not currently market electronic monitors, the capital equipment that processes the electrical signals. In addition to products currently offered, UTMD intends to continue to investigate and introduce tools that enhance fetal monitoring techniques.

Vacuum-Assisted Delivery Systems (VAD).

UTMD's VAD Systems include CMI® patented soft silicone bell-shaped birthing cups and patented hand-held vacuum pumps which UTMD believes are the safest products available for use in vacuum-assisted operative deliveries. UTMD's patented soft silicone cup is a bell-shaped cup design that should be preferred for fetal well-being in low or outlet fetal stations with occiput anterior presentations, which represent more than 90% of the cases where VAD is indicated. Operative vaginal deliveries using forceps or vacuum-assisted delivery systems provide knowledgeable physicians with a trial vaginal operative delivery prior to a more invasive C-section intervention. Although there are risks associated with vaginal operative deliveries which may currently represent 3-5% of all U.S. hospital births, the procedures are generally regarded as safer long term for the mother, and at least as safe for the fetus, as abdominal (Cesarean) delivery in comparable clinical situations. UTMD estimates that the VAD operative approach is used for about 3-5% of all U.S. births, with forceps as the alternative. UTMD's bell-shaped soft silicone TENDER TOUCH® cups enjoy a low reported complication rate compared to other vacuum cup designs, as evidenced by the FDA Medical Device Reporting System (MAUDE) which publicly lists serious injuries reported by hospitals using specific brand names of products.

Other Obstetrical Tools.

AROM-COT™ is a finger cover with a patented prong design to rupture maternal membranes with less patient pain and anxiety. MUC-X is an aspiration device used immediately after birth to clear neonatal respiratory passages and reduce exposure to potential infections. CORDGUARD® is a product which unifies the multiple steps of clamping the neonate's cord close to the umbilicus, severing the cord without splattering blood, drawing a clean cord blood sample, and assisting in the removal of the placenta. CORDGUARD's sharpless, closed system reduces the risk of exposure to potentially infected blood, and consequently reduces the high cost of exposure treatment under OSHA and CDC guidelines. In addition, CORDGUARD facilitates obtaining neonatal blood that is otherwise hard to obtain safely and cleanly. BT-Cath® is a patented uterine balloon tamponade catheter for controlling severe postpartum hemorrhage. Its benefits include the ease of rapid deployment and ability to monitor further bleeding after the tamponade has been placed. Abcorp toco belts and straps for fetal monitoring by an external tocodynamometer are provided in latex-free form in several configurations. In 2014, UTMD extended the product line to include Bari-Belts™ and Bari-Bands™, a series of abdominal belts designed specifically for bariatric patients and bands to accommodate patients of all shapes and sizes.

Neonatal Intensive Care:

DISPOSA-HOOD™

The DISPOSA-HOOD is an infant respiratory hood that is used in the NICU to administer oxygen to neonates and flush CO₂ (carbon dioxide) while maintaining a neutral thermal environment (NTE) critical to proper physiologic responses. The DISPOSA-HOOD, placed over the infant's head, incorporates a round diffusor connection specifically designed to disperse the incoming gases along the inner surfaces of the hood, rather than allowing them to blow directly on the infant's head. The design allows more precise FIO₂ (fractional inspired oxygen) control, minimizes convective heat loss from the head, provides optimum flows for elimination of CO₂ by ventilation and allows for humidification. DISPOSA-HOOD, in contrast to an incubator, allows for excellent access to and visualization of the underdeveloped infant. Because it is a disposable product, it also prevents potential cross-contamination that might occur with an incubator. Less invasive and constraining than nasal cannulae, Disposa-Hood avoids potential damage to fragile premature neonatal nasal/ orotracheal tissues, as well as facial tissues as cannulae are often secured with tape. Of course, a nasal cannula by itself cannot provide a NTE.

DELTRAN® PLUS

UTMD's DELTRAN blood pressure monitoring system has been adapted specifically for use in the NICU. The streamlined version eliminates needles used for blood sampling, avoids the loss of scarce neonatal blood volume and provides a closed system that reduces the risk of infection. The system features excellent visualization of clearing volume, and one-handed use. UTMD continues its customization of Deltran kits for specific hospital applications.

GESCO®

In the third quarter of 1998, UTMD acquired the neonatal product line of Gesco International. GESCO, best known for optimally biocompatible silicone catheters, gained an early distinctive reputation for its focus on the special developmental needs of tiny, critically-ill babies.

A class of catheters called umbilical vessel catheters (UVCs) are specially designed for administering vital medications and fluids immediately following birth through the infant's umbilical vessel into the inferior vena cava. Because of the neonate's small size and lack of vascular development, there is no better access to vital organs. The catheters are also called umbilical artery catheters (UACs) when placed in one of the umbilical arteries to measure blood pressure or monitor metabolic processes through blood analysis. In developing its UMBILI-CATH™ product line, Gesco pioneered the use of soft, biocompatible silicone catheters, helping to reduce the number of insertions required as well as other complications associated with invasive applications. UTMD has expanded the UVC product line to include catheters made from a proprietary thermosensitive polyurethane (Tecoflex®) that offers

many of the flexibility and biocompatibility advantages of silicone after insertion, with the greater rigidity of polyurethane preferred by many clinicians for ease of insertion. In addition, GESCO provides a convenient catheterization procedure tray of implements and supplies necessary to place UVC catheters, as well as perform other similar procedures.

The primary distinction of GESCO products is that they were developed with the special needs of the neonate in mind, not just cut-down or smaller versions of adult devices. For example, in the case of invasive catheters, the introducer, the soft rounded distal tip, mode of securing to the patient after insertion to avoid migration, luer-locking hub with minimal dead space, number of lumens, catheter radiopaque striping for visualization, variations in catheter lengths and diameters and special packaging are all features specially designed for neonates. UTMD continues to modify product features to incorporate current neonatal nurse practitioner preferences.

The soft, biocompatible silicone catheter concept had important advantages in other applications including peripherally inserted central venous catheters (PICC lines), enteral feeding tubes, urinary drainage catheters, and chest drainage tubes. GESCO developed and marketed initial versions of all of these neonatal products. In order to keep pace with the trend of caring for smaller babies, UTMD has added smaller diameter versions of its URI-CATH® and NUTRI-CATH® products. At the request of customers who prefer a stiffer catheter for insertion, UTMD added a Tecoflex polyurethane oral-connection only Nutri-Cath series in 2009.

In 2000, UTMD gained FDA premarketing clearance of a PICC family of products specifically designed to minimize trauma to the critically ill neonate, named PICC-NATE®. The PICC-Nate product line was designed with the input of experienced neonatal nurse practitioners for use as a long-term indwelling catheter system for single-use, therapeutic central venous infusion of drug solutions, blood products or other fluids and for blood sampling. The soft, strong silicone PICC-Nate comes in two diameter sizes and two hub configurations. In early 2003, UTMD added a Tecoflex polyurethane version that offers many of the flexibility and biocompatibility advantages of silicone after insertion, with the greater rigidity of polyurethane preferred by many clinicians for insertion.

In 2006, UTMD developed a unique enteral feeding-only extension set named NUTRI-LOK® that addresses important safety risks in the NICU – inadvertent connections with IV lines and inadvertent disconnections of components of the system spanning the dispensing container through the infusion catheter. NUTRI-LOK was launched to the market in January 2007. In October 2007, UTMD added dispensing syringes with interlocking connectors to its NUTRI-CATH/NUTRI-LOK family of enteral feeding devices. In 2008, UTMD expanded the NUTRI-LOK system with specialty extension sets for GI tubes and for continuous connection to a fluid pump. In 2009, UTMD added a Kangaroo bag for larger feeds along with other NUTRI-LOK accessories. In 2011, UTMD added variations in adapters and extension sets used with NUTRI-CATH.

In 2006, UTMD completed the replacement of all DEHP plasticizer PVC materials in its Gesco product line that may come in contact with neonatal patients, addressing another evolving safety concern related specifically to the possible maldevelopment of male neonates.

Other GESCO specialty products include a disposable peritoneal dialysis (PD) set that is a pre-assembled, sterile, closed system, called DIALY-NATE®. PD is an ideal method to aid compromised renal function in a neonate because critically-ill pediatric patients may not have sufficient blood volume to support hemodialysis. DIALY-NATE is provided in a form that allows timely PD implementation. In 2008, UTMD added a DIALY-NATE version that can be used with a variety of fluid warming systems. In 2010, UTMD introduced a bifurcated system that allows for higher volume manual PD applications. In 2013, additional custom configurations were added to satisfy specific clinical preferences.

Other specialty NICU devices include a patented silicone oral protection device used to prevent palatal soft tissue injury by orotracheal tubes, called PALA-NATE®; a pre-assembled, closed urinary drainage system, called URI-CATH®, which reduces risk of infection and valuable nursing time, and a lumbar sampling kit with a tiny, specially-beveled needle for obtaining cerebral spinal fluid samples, called MYELO-NATE®.

GESCO's first patented product, HEMO-NATE®, is a disposable filter designed to remove microaggregates from stored blood prior to transfusion into a neonate where any deficiency can have an overwhelmingly negative impact on a neonate's chances for survival, given an under-developed vasculature and small total blood volume. In 2001, UTMD introduced a new filter and an improved blood bag spike for Hemo-Nate, and a needleless version.

UTMD expects to continue to improve and expand its neonatal product line, seeking to reinforce a reputation as having the most developmentally-friendly specialty products available for the NICU.

Gynecology /Urology /Electrosurgery:

LETZ® System

The LETZ System (loop excision of the transformation zone) is used to excise cervical intraepithelial neoplasia (CIN) and other lower genital tract lesions related to human papilloma virus (HPV) infections. The electrosurgery procedure with hemostasis has become the standard of care for HPV cervical infection treatment, replacing cold knife scalpel, laser and cryotherapy procedural approaches because it is economical, safe, effective, quick and easy to perform, has fewer potential side effects and requires little physician training. A major incentive for performing the LETZ procedure is that it may be performed using local anesthetic in a physician's office, eliminating the time and expense of hospital or surgical center admittance. Most importantly clinically, in contrast to laser (tissue ablation) and cryotherapy (freezing of tissue), LETZ provides a fine tissue specimen for pathological assessment.

UTMD's LETZ System includes patented disposable electrodes, the FINESSE® electrosurgical generator and other miscellaneous components. A disposable loop electrode used to excise the tissue specimen is a pencil-like tube with a thin tungsten wire loop attached. The loop is available in varying sizes and includes a Safe-T-Gauge® that can be positioned so the physician can accurately colposcopically monitor the amount of tissue being excised. Excising too much tissue can compromise fertility and result in premature birth. UTMD continues to augment its specialty electrodes. For example, the Company introduced a patented conization electrode for deep endocervical disease called C-LETZ®, designed to limit the removal of healthy tissue margins that might compromise adequate cervical function. UTMD also will continue to provide adapters and other components which allow its market-leading specialty electrodes to be used with other manufacturers' electrosurgical generators.

After more than 20 years on the market, in 2012 UTMD completed a significant redesign, and achieved certification to the latest EN 60601 international safety standards, for a new FINESSE+ electrosurgical generator. The new Finesse+ design includes dispersive pad contact monitoring for improved patient safety, improved circuitry for computer controlled-output that provides a precise tissue specimen for histopathology, a more efficient output stage resulting in less heat generation and longer electronic component life, an update to modern electronic components which reduces the number of required components and increases service life, and an easy change internal filter for integral smoke evacuation, a unique feature of Finesse. UTMD obtained FDA premarketing clearance for Finesse+ in January 2013.

FINESSE+ Generator; Specialty Loop, Ball, and Needle Electrodes; FILTRESSE® Evacuator; Other Specialty Electrodes; Other UTMD Supplies and Gynecologic Tools; Femcare Trochars and Cannulae; and Femcare Laparoscopic Instruments and accessories.

UTMD has FDA clearance to market its electrosurgical system and tools for use in general surgery applications, including dermatology, plastic surgery and otolaryngology. In 2002, UTMD introduced a product line of ultra-fine tipped microdissection needles, called OptiMicro™ Needles. These electrosurgical needles are particularly useful in small-scale plastic and reconstructive surgery applications. In 2009, UTMD added extended length OptiMicro needle versions useful in certain head and neck procedures. FILTRESSE is a stand-alone surgical smoke filtration system that combines high filtration efficiency, low cost and convenient use in a surgical office setting. Other electrosurgery tools and accessories include disposable electrosurgical pens, dispersive pads, footswitches, filter packs, speculums, retractors, forceps, tenacula and hooks. UTMD acquired the distribution rights to a unique reusable four-way expander system which facilitates access to, and visualization of, the cervix, eliminating the need for less effective specula and lateral retractors. In 2007, UTMD developed OptiSpec®, a patented ultra-bright light for cervical visualization without physician distraction during exams, pap smears and other vaginal procedures requiring direct cervical visualization without the use of a colposcope. In 2009, UTMD entered into a distribution agreement for the CompuMed anesthesia injection system for providing computer-controlled, accurate, and pain-free injection of Lidocaine in LETZ procedures. In 2011, UTMD acquired Femcare's single patient use trochars and cannulae available in shielded, bladeless, optical bladeless, blunt and thoracic designs. In addition, UTMD acquired Femcare's laparoscopic instrument range and accessories which includes instruments suitable for all routine laparoscopic procedures requiring dissection, cutting, grasping and coagulation, e.g., monopolar scissors, various grasping forceps, dissecting forceps, L and J hooks, spatulae, Verres needles, suction and irrigation tubing, insufflation tubing and connectors, pressure infusor bags and control valves.

EPITOME®

EPITOME is a patented electrosurgical scalpel which delivers precise performance in incision and excision with hemostasis while minimizing thermal side effects. Where rapid yet precise dissection of dense tissue is necessary, such as in mammaplasty or abdominoplasty, UTMD believes that EPITOME has no close substitute. Furthermore, an independent study concludes that the EPITOME scalpel provides a significant improvement over older devices in wound healing and patient comfort. EPITOME allows a rapid incision without countertraction, yielding limited

morbidity, less post-surgical pain and cosmetically superior results. EPITOME is useful where minimization of thermal tissue injury is important but control of bleeding needed. A patented bendable version of EPITOME with a smaller active electrode was introduced in 1998. Designed to significantly reduce the chance of tissue burns due to inadvertent electrode contact and where a smaller, bent scalpel tip is needed, the bendable EPITOME is of particular value, e.g., to thoracic surgeons in harvesting the internal mammary artery during coronary artery bypass surgery, as well as to otolaryngologists for tonsillectomies or uvulopalatalplasties.

FILSHIE CLIP System

UTMD acquired the Filshie Clip System as part of its acquisition of Femcare in March 2011. In 2014, sales of Filshie Clips, applicators and accessories represented 38% of UTMD's total sales. The Filshie Clip is a female surgical contraception device used for tubal ligation, i.e., placed on the fallopian tubes, generally laparoscopically but also post partum during a C-Section procedure. The Filshie Clip, in use for over 30 years, is as effective as the newest occlusive devices and much more effective than the more traditional tubal ligation sterilization approaches, is as easy or easier to place as any of the traditional techniques and much easier than the newer hysteroscopic devices, is safer than electrocautery and the newer hysteroscopic devices when placed by less than well-trained and skilled clinicians, and has a substantially higher probability of reversibility when compared to all of the other approaches for women who later decide they may like to get pregnant.

There are several tubal ligation methods with varying degrees of effectiveness, safety and opportunity to be reversed. The traditional tubal ligation approach, informally known as "getting one's tubes tied", is a form of female sterilization in which the fallopian tubes are severed and sealed, permanently occluded or pinched shut. If the sterilization procedure is carried out at post-partum, the Pomeroy technique is often adopted. During this procedure a small loop of the fallopian tube is tied with a suture and the top section removed by cutting. A traditional method for interval sterilization is with the use of Bipolar Cautery (electrocautery). With this method, a current flows between the tips of forceps when applied to the fallopian tube. This current then "burns" a portion of the fallopian tube shut. Although these common methods are relatively easy to perform, the "failure rate" of these methods, defined as the percentage of patients having undergone the procedure who subsequently get pregnant, has been reported to be about 3%. The Filshie Clip, which can be used at either interval or post-partum, is at least as easy to use and has a failure rate an order of magnitude less than Bipolar Cautery and the Pomeroy technique.

Apart from Bipolar Cautery and the Pomeroy technique, other mechanical devices are the Falope Ring (or Yoon Ring) and the Hulka Clip. Both these older methods have a higher failure rate than the Filshie Clip, are associated with more post-operative pain and have generally been abandoned in favor of other sterilization techniques. Sterilization carried out with the Falope Ring also reduces the chances of a successful reversal being carried out.

In more recent years, hysteroscopic sterilization has been introduced as an alternative to laparoscopic tubal ligation. The device is the ESSURE by Conceptus, Inc. The device, considered a permanent implant, is inserted transvaginally. Although similar to the Filshie Clip in its sterilization effectiveness as measured after successful application, Essure takes some time after placement to become effective, requires an additional subsequent procedure to confirm that the tubes are blocked, is not reversible (allowing later pregnancy) and requires much more skill to apply correctly. Essure's reported misapplication rate and post-operative pain are significantly greater than using the Filshie Clip.

The U.S. FDA released the Filshie Clip for marketing in 1996 after a Femcare PMA submission. Now the Filshie Clip is effectively marketed in the U.S. through an exclusive distribution agreement with CooperSurgical Inc. (CSI). In 2014, sales to CSI for use in the U.S. were 24% of total Filshie Clip System sales. Outside the U.S., the Filshie Clip has numerous regulatory approvals and is being sold directly by UTMD to clinicians in Ireland, the U.K. and Australia, and through specialty distributors in other countries.

PATHFINDER PLUS™

PATHFINDER PLUS is a proprietary endoscopic irrigation device that allows a uro/gyn surgeon to precisely irrigate, clearing the visual field, with the same hand that controls the endoscope, eliminating the need for a separate assistant to irrigate without visualization. An example of a procedure where Pathfinder has found success is ureteroscopic stone ablation.

LAWRENCE ADD-A-CATH

The Lawrence Add-a-Cath introducer is a proprietary Femcare device designed for easy suprapubic introduction of a catheter for bladder drainage. Suprapubic catheterization is generally well-recognized as a drainage method with fewer complications than with urethral catheterization. Previous to UTMD's acquisition of Femcare, it was distributed in the U.S. through an OEM customer. In 2013, UTMD introduced suprapubic catheterization procedure kits featuring the Lawrence Supra-Foley introducer which it now distributes directly to end users in the U.S.

HOLMIUM LASER FIBRES

As part of its urology product line, Femcare distributes reusable and single patient use laser energy delivery devices which can dependably transmit both the Holmium and Nd:YAG wavelengths.

LIBERTY® System

LIBERTY is a device for the conservative treatment and effective control of urinary incontinence in women. UTMD believes that LIBERTY is the easiest-to-use, most cost effective incontinence treatment available that yields a therapeutic effect, not just a cover-up. LIBERTY consists of a battery operated electrical stimulation unit and an intravaginal electrode probe. This physiotherapy technique, which can be done in the privacy of the home, involves passive strengthening of the periurethral muscles. Pulsed, low voltage, high frequency current is applied primarily to the pudendal neuromuscular tissue causing the pelvic area muscles to contract, leading to better muscle tone. Because electrical stimulation has no known adverse side effects, LIBERTY provides women suffering from mild to moderate incontinence an effective, lower cost and lower risk alternative to more traumatic treatments such as surgery and drug therapy.

ENDOCURETTE™

In cooperation with Mayo Clinic, UTMD developed an advanced curette for uterine endometrial tissue sampling in the doctor's office. The sampling procedure is intended primarily to rule out precancer or cancerous change of the uterus in premenopausal women with abnormal uterine bleeding, or women with postmenopausal bleeding. The device is part of a class of catheters designed to be used without dilatation of the cervix and without general anesthetic. The inherent weakness of this type of device, which is related to its small size, is that it may not remove enough tissue of the endometrium for an accurate histologic assessment, in contrast to a more invasive D&C hospital procedure. The patented tip of the EndoCurette was designed to obtain a more thorough tissue specimen without the need for dilatation, and without an increase in patient discomfort.

TVUS/HSG-Cath™

In order to further assess persistent abnormal or dysfunctional uterine bleeding and other suspected abnormalities of the uterus, or as a next step after endometrial tissue sampling with an EndoCurette, gynecologists are increasingly utilizing transvaginal ultrasound imaging of the uterus. UTMD's TVUS/HSG-Cath was designed and released for marketing in 2007 to provide effective cervical occlusion that allows distention of the uterus to differentiate anterior and posterior endometrium, among other irregularities, together with minimal visual obstruction of the uterus near the internal os. In addition, the TVUS/HSG-Cath may be used in hysterosalpingography radiographic procedures to assess the patency of fallopian tubes. A related device acquired in 2011 is Femcare's Spackman Style uterine cannula designed for the manipulation of the uterus and injection of fluid to test the patency of the fallopian tubes.

LUMIN®

LUMIN® is a patented gynecological tool developed by UTMD for reliably and safely manipulating the uterus in laparoscopic procedures. LUMIN combines the strength, range of motion and versatility of the higher end reusable instruments with the lower cost and cleanliness of the inexpensive less functional disposable instruments presently on the market, while at the same time reducing the number of tools needed to move and secure the uterus.

Blood Pressure Monitoring:

DELTRAN® Disposable Pressure Transducer (DPT)

In pressure monitoring, a transducer is used to convert physiological (mechanical) pressure into an electrical signal that is displayed on electronic monitoring equipment. UTMD developed, patented and is now distributing its disposable transducer as a stand-alone product, and as a component in sterile blood pressure monitoring kits through direct representatives and other medical companies in the U.S., as well as independent distributors and other medical device companies internationally.

The Company believes that the DELTRAN DPT which it designed over twenty-five years ago (original patents have expired), and currently manufactures, remains the standard in terms of accuracy, reliability and ease of use. UTMD has an automated assembly line which allows the Company to effectively compete with larger suppliers on the basis of consistent quality and low manufacturing costs. Introduced in 1998, the DELTRAN PLUS provides a closed system for blood sampling, without the use of needles, reducing the risk of an unwanted infection for both the patient and the practitioner. In 2009, in conjunction with its other NICU devices, UTMD continued to configure neonatal Deltran custom kits which satisfy the special needs of conserving limited blood volume and protecting the neonate from infection.

Pressure Monitoring Accessories, Components and Other Molded Parts.

Components included in blood pressure monitoring kit configurations include flush devices, stopcocks, fluid administration sets, caps, pressure tubing, interface cables and organizers. The Company sells similar components designed for other medical device company applications which incorporate UTMD's technologies and designs. DELTA-CAL™ is a calibration device used to check proper functioning of an arterial pressure system. In addition, UTMD sells plastic molded parts on a subcontract basis to a number of medical and non-medical device companies. In addition, partly as a result of its excellent quality system and ISO13485 certification, UTMD performs subcontract assembly, testing and packaging of components that are proprietary to other medical device firms. UTMD believes that this practice helps better utilize its investment in fixed plant and equipment, and spreads overhead costs resulting in better profit margins on finished device sales.

MARKETING and COMPETITION

UTMD divides its sales into "domestic" U.S. sales and "international" sales, which are finished device and component sales to entities outside the U.S.

In the past, UTMD has divided domestic U.S. sales into "direct sales" and "OEM sales." Included in direct sales have been sales of finished devices through hospital distributors. OEM sales are theoretically to other medical device (or non-medical device) companies where UTMD products are components of their finished product offerings. The distinction starts to blur when distributors purchase components or finished devices that they relabel or market as part of a kit, or other medical device companies purchase finished devices that they sell as a distributor. A significant recent example is the Filshie Clip System sold to CSI by Femcare-Nikomed Ltd, a subsidiary of UTMD, under a distribution agreement for the U.S. Because CSI is another medical device company, UTMD has included these sales in its Domestic OEM Sales category since the 2011 acquisition of Femcare. However, CSI is really a distributor of Femcare's finished devices. The regulatory responsibility is Femcare's with respect to product safety and effectiveness. However, from a marketing perspective, labels include both the Femcare and the CooperSurgical names. UTMD could classify the sales as domestic direct because CSI is a distributor of UTMD's subsidiary finished devices, or as domestic OEM because CSI is another medical device company which has its name on the label. As sales of components to non-medical device entities are immaterial, UTMD will no longer try to make the distinction between domestic direct sales and domestic OEM sales. As an observation, UTMD stopped trying to make the distinction for its international sales over a decade ago, because a greater portion of its international sales were to foreign "distributors" which are difficult to classify as either direct or OEM.

1) Domestic sales.

For domestic sales to end-users of finished devices, marketing efforts are complex and fragmented. UTMD's marketing focus is with clinicians who take responsibility for obtaining optimal patient care outcomes, primarily through clinical meetings, trade shows and the Internet. In competitive bidding processes, UTMD works primarily with administrators who are responsible for hospital purchasing decisions.

UTMD competes primarily on the basis of improved patient safety and reliable device performance in the hands of a trained clinician. A number of UTMD's devices are strong brands because they are well-recognized by clinicians as clinically different and have been in use for decades. UTMD's broad offering of finished devices is comprised of dozens of specialty device types. Although there may be only a few competitors for each type, in the aggregate UTMD has dozens of U.S. medical device competitors. There are at least two competitors with significant market share for each of UTMD's device types.

As a general rule, because of UTMD's differences in design and manufacturing reliability, competitors' devices represent substitutes rather than equivalent devices. The Company's primary marketing challenge is to keep its customers focused on those differences and their important clinical benefits. In recent years, UTMD's access to U.S.

hospital clinicians has become increasingly restricted and the involvement of clinicians in medical device purchasing decisions, which is critical to the Company's success, has declined. To the degree that U.S. hospitals become less focused on patient safety and clinical outcomes and more on out-of-pocket unit price, UTMD's competitive position weakens.

In 2014, UTMD sold components and finished devices to 142 other companies in the U.S. For over 35 years, the Company has utilized its manufacturing capabilities and engineering know-how to produce high quality components and finished devices for other companies. For U.S. companies which wish to distribute their products outside the U.S., UTMD's maintenance of certification to current ISO 13485 medical device quality standards is an important benefit. UTMD's website, which lists its capabilities, is often the basis for contacts for new OEM work.

Although there are other manufacturers in the U.S. with similar manufacturing capabilities, UTMD's primary competition comes from East Europe, India and China device component manufacturers which have much lower wage rate structures. To the extent that the U.S. Dollar gains strength in any period of time against foreign currencies, UTMD's ability to be cost-competitive with foreign manufacturers is additionally diminished.

2) International sales.

In 2011-2014, international sales represented a majority of consolidated total sales. Prior to 2011, with only a few exceptions, UTMD's international sales were to other medical device companies and distributors, not to clinical end user facilities. After the acquisition of Femcare in 2011, UTMD began a transition to selling direct to end user facilities in the UK, Australia and Ireland, which has had a positive impact on revenues as well as gross profit margins. UTMD expects that international sales will continue to grow more rapidly than its domestic sales, as the standard of living in emerging countries continues to improve. UTMD's website provides information that frequently results in unsolicited contacts from foreign entities. The Company has hundreds of competitors worldwide.

DISTRIBUTION

An important success factor in the current U.S. healthcare industry is access to customers. Although the U.S. hospital supplier environment has been consolidating as a result of group purchasing organizations (GPOs), or their equivalents, the financial relationships and true benefits for hospitals has come under scrutiny, both by hospitals' managements themselves and by the government. As a potential positive factor to UTMD's future performance, the increased scrutiny may lead to an understanding consistent with UTMD's belief that U.S. hospitals are not currently saving costs under GPO contracts when it comes to specialty medical devices that can reduce complications and unwanted side effects.

In addition, the longer term overall cost of care in the U.S. will continue to increase, with quality of care lower, as innovative suppliers are excluded from participating in the marketplace as a result of unnecessary regulatory and other purely administrative burdens, as well as the medical device excise tax levied under the 2010 Patient Protection and Affordable Care Act. The length of time and number of administrative steps required in evaluating new products for use in hospitals has grown substantially in recent years. As a potential negative factor to future performance, as UTMD introduces new products it believes are safer and more effective, it may find itself excluded from certain customers because of the existence of long term supply agreements for existing products. UTMD may also be unable to establish viable relationships with other medical device companies that do have access to users but lack an interest in the Company's approach or demand too great a financial or administrative burden.

When U.S. hospital customers request it, UTMD provides its products through national distribution companies, also known as Med/Surg distributors. Sales to Med/Surg distributors currently comprise about 14% of total domestic direct sales (excluding Filshie Clip sales to CSI).

In the U.S., Ireland and UK, UTMD sells its products through its own directly employed sales force and through selective independent manufacturer representatives. Direct sales representatives focus on applications for UTMD devices where customer training and support may be important. The direct sales force is comprised both of "outside" representatives operating remotely in specific geographic areas, and "inside" representatives who operate primarily by telephone from corporate offices. Direct representatives are trained to understand the medical procedu