

ENIWARE, LLC BUSINESS PLAN

Portable, Power-free, Room Temperature Sterilization

AUGUST 2018



"What is the delay? We need it immediately."

*-Nurse Musabyimana Goretti,
Gasiza Health Center, Rwanda*



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EXECUTIVE SUMMARY

1. INTRODUCTION

Eniware's clear and specific mission goals directly address an urgent global need: To enable health professionals worldwide to provide **safer, infection-free, sterilized surgical instruments for health care for all those in need, anywhere, at any time, and to support safe essential surgery around the world.** We envision a world where everyone has access to infection-free health care whether in New York City, a rural village in Uganda, a military's far forward surgical unit, or on the frontlines of a natural disaster.

2. THE PROBLEM

Currently there is no sterilization solution in areas, which have no electricity, or intermittent electricity. Safe surgery is not possible without effective sterilization of medical instruments.

Affordable and effective sterilization of surgical instruments and devices, addresses three interrelated challenges to global health:

- Preventing disease transmission
- Expanding primary surgical care
- Reducing healthcare associated infection (HCAI)

The sterilization challenge is best understood as an ever-expanding effort to provide safe, high quality health care in any setting. Affordable sterilization could lower barriers to expanding care and dramatically reduce the global burden of disease.



Because electricity is unpredictable and in short supply in much of the world, and because current sterilization technologies consume large amounts of power, a large part of the world relies on disinfection

which does not kill spores and thus does not meet the needs of surgery.

In 2015, responding to a growing awareness that the global burden of disease was a serious and growing problem, the global health community identified the lack of access to and availability of basic safe essential surgery as a critical problem. In response to this deficit and further amplified by WHO, the Lancet Commission on Global Surgery was established.

SUMMARY

Problem

- ❖ Safe basic surgery is not possible without sterile instruments
- ❖ No power-independent sterilization currently available
- ❖ Significant portion of global disease burden treatable by surgery

Solution

- ❖ NO₂ A powerful sterilant gas.
- ❖ Noxilizer patented technology exclusively licensed to Eniware.

The Eniware Potable Sterilizer (EPS-25) delivers affordable, portable sterilization without electricity, water and at room temperature

Management

James Bernstein, MD, CEO & Medical Director
Huma Malik, Co-Founder, President, COO

Out Sourced Services

Harbor Designs and Manufacturing
Agalloco & Associates (agalloco.com)- Sterilization
Emergo; Regulatory
Logenix Int'l: Logistics

Board of Directors

James Bernstein, Chairman
Huma Malik, Co-Founder, President
Ian Clarke, Chairman IMG Uganda, CEO, Clarke Group, Chairman East Africa Health Federation
Michael Steele, Former RNC Chairman, Former Lt. Governor, Maryland, and Steele Group Inc.
Terry Lierman, Partner, Summit Global Ventures
Jeffrey Leonard, CEO & Co-Founder, Global Environment Fund

Industry: Medical Technology/Global Health

Financial: Bank of America

Legal: Pillsbury Law, LLP and 3rd Gen Law Group

Funds Sought: Up to \$1 million

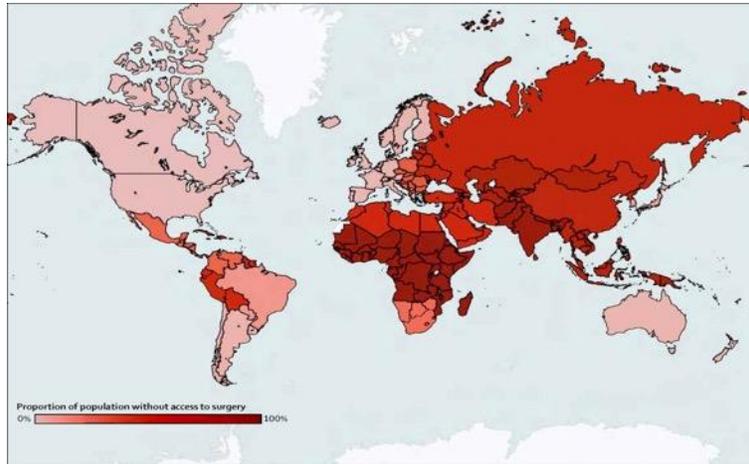
Current Investors: Erindale Investments Ltd., Individuals, Family offices.

Use of Funds:

- ❖ Product Launch
- ❖ Market Roll-Out
- ❖ Manufacturing Ramp Up
- ❖ Contingency

Relying on a global network of experts and previous data analyses, the Commission has documented the following:

1. 5 billion people do not have access to safe affordable surgical care. In low and middle-income countries (LMIC'S) 90 % of the population cannot access basic surgical care.



2. About 150 million additional surgical procedures are needed in LMICs each year with the need greatest in sub Saharan Africa, and South Asia. (Note: Estimated 33 million surgeries done annually with only 6% done in LMICs where 33% of the world's population lives)
3. Close to 100 million people a year face catastrophic costs associated with either the provision of or accessing surgical care. Most of these people are poor and in LMICs.
4. Losses in economic productivity in LMICs due to this shortfall in surgical services are estimated at US \$12.3 trillion over the next 15 years.

“Surgical conditions-whether cancers injuries, congenital anomalies, childbirth complications or infectious disease manifestations- are ubiquitous, growing, and marginalizing to those who are affected by them. These conditions are financially devastating for individuals and their families, economically damaging for countries, and disproportionately threaten the welfare of the poorest most vulnerable people in our societies. To promote health and well-being of people of all ages will need widespread and equitable provision of surgery and anesthesia, the treatment needed for one third of the world’s population” Lancet Commission

Investing in surgical services in LMICs makes abundant economic sense. The target is 5,000 surgical procedures/100,000 population.

5. Surgical services are a must part of any integrated health system and are critical to reach global goals in cancer, injuries, cardiovascular disease, infection, reproductive, maternal, neonatal and child health.

The requirements for safe essential surgery are fourfold: available manpower capable of performing necessary operations, the capacity to provide anesthesia (local, spinal, general), **critical need for sterile instruments and processes** and adequate financing through health insurance.



Great strides have been made in all areas except for sterilization. It should be apparent that absent sterile instruments, even trained surgical staff and anesthesia availability will not suffice. Existing approaches consume large amounts of electricity, need deionized water, are prone to break frequently, are expensive and are thus often non-functional. What is required urgently is an easy to use sterilizer that can function in the absence of electricity that requires little or no maintenance and is affordable and safe.

The need for power-independent sterilizers exists not only in the developing world but also in those environments where power is limited or not available; i.e. disaster relief zones, refugee camps, and forward military bases.

The human cost of lack of sterilization is shown below. These women died or were disabled solely due to the lack of safe surgery and in both cases the results were totally preventable.



These three women in Tanzania developed obstructed labor and did not have access to Caesarean section. The result was an obstetric fistula where they are doomed to living with a tube draining into a green plastic bucket for the rest of their life unless they can get corrective surgery.

There are an estimated 3 million such women in the world today. 2-3 % of all complicated labor ends like this without access to safe surgery.



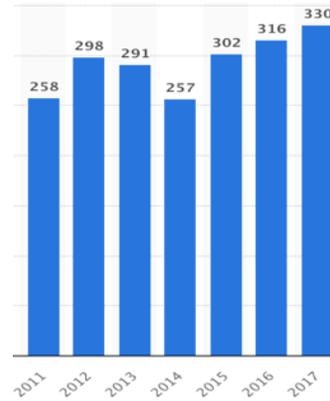
This young Afghan woman had just delivered her baby by Caesarean section. The problem was that the instruments were disinfected, not sterilized. 9 days later she died from sepsis. Again cases like this are totally preventable with access to sterile instruments.

The number of natural disasters has been increasing relentlessly leading to many occasions that require immediate surgical response where there is no electricity.

Good examples here in the US are the result of major hurricanes. Puerto Rico, Houston, TX, Florida have all suffered the wrath of hurricanes and the critical need for sterilization without electricity.



Puerto Rico Hurricane Maria 2017



No. of Natural Disasters

And finally, the refugee crisis creates a large and growing need for basic primary health services including safe surgery. There are over 25 million refugees globally with 85% in developing countries. This number grows by 44,000 per day. Power is in critically short supply in refugee camps.

3. THE SOLUTION: The Eniware Portable Sterilizer

Eniware has addressed this problem head-on and has developed, validated and is poised to ramp up manufacture the first ever sterilizer that uses no electricity, heat or water, is affordable, safe, reliable and easy to use.

The Eniware Portable Sterilizer (EPS-25) is a stand-alone device designed for use in low resource settings to:

1. Sterilize surgical instrument sets
2. Sterilize specialized equipment used in hospital settings
3. Diagnostic laboratory glassware.

The EPS-25 has completed a rigorous design, engineering, prototype and manufacturability process according to ISO and QMS standards.

1. Design specifications were developed after extensive market research and Voice of the Customer field research in East Africa over a two-year period. Health Facilities Visited by Dr. Bernstein and Huma Malik

Kenya: Kenya Medical Research Institute (KEMRI), Nairobi City; Kenyan Red Cross, Nairobi; Kijabe Hospital, Kijabe; Mission for Essential Drugs and Supply, Nairobi; Nakuru provincial hospital, Nakuru; Mama Lucy Kibaki Hospital, Nairobi; Kigumo Health Centre, Muranga; Muranga District Hospital, Muranga; Kiriaini Mission Hospital, Kiriaini

Rwanda: Butaro District Hospital, Burera district, Rwanda; Central University Teaching Hospital (CHUK), Kigali; Ruhengeri Hospital, Ruhengeri; Rwanda Biomedical Center (RBC), Rugenge, Kigali; Rwanda Military Hospital, Kanombe, Kigali

Tanzania: Luduga Dispensary, Njombe; Makambako Town Hospital, Makambako, Njombe; Ministry of Health, Dar es Salaam; Regional Administrative Healthcare Office, Njombe; Usalule Dispensary, Njombe; Ya Halma Shuri Ya Mji, Njombe; Sekou Toure Hospital, Mwanza; Bugando Medical Centre, Mwanza; Sengerema District Hospital, Sengerema; CCBRT Hospital, Msasani.

Uganda: Alive Medical Services, Kampala; International Hospital Kampala (IMG), Kampala; Joint Medical Store, Kampala; Kibuli Islamic Hospital, Kampala; Mengo Hospital, Mengo; Mulago Hospital, Kampala; Virika Hospital, Fort Portal

2. Final engineering and prototyping was carried out in Baltimore with our partner and contract manufacturer, Harbor Designs and Engineering. This effort required developing complex solutions to sterilant gas generation that met IATA and IMDG standards as well as developing unique scrubber consumables. Fail- safe safety has been incorporated as well.
3. The initial prototype has been reengineered to permit scalable and inexpensive manufacturability and is now manufacture-ready.

The EPS has been validated and cycle parameters have been developed, tested and validated under the direction and supervision of James Agalloco, a leading internationally recognized expert in sterilization validation. (Agalloco Associates)

1. Basic microbiology has been executed to select the appropriate biological indicator (BI) test system for validation testing.
2. Key sterilization parameters for validation including cycle time, relative humidity and temperature have been tested, evaluated and incorporated into cycle design.
3. The EPS-25 has been validated using selected instrument sets at boundary conditions of temperature and relative humidity.



BIs

Ease of Use Studies has been carried out in Sierra Leone.

1. 24 surgical nurses were trained and tested the EPS-25 over a two-week period in conjunction with the Johns Hopkins Medical School and the Bloomberg School of Public Health.
2. No deficits or functional problems were encountered.



Dr. Agalloco over seeing microbiology testing at METLABS

Regulatory Issues

Eniware is ISO13485 certified. The company has a well-functioning Quality Management System (QMS).

The EPS-25 will be CE marked after the company completes its submission carried out with the assistance of Emergo, a Global Medical Device Consulting company and with the notified body, BSI.

IP

The company has acquired a set of licenses for use of the NO₂ patented technology from Noxilizer, a company that was founded by Dr. Bernstein and which has commercialized, FDA cleared and CE marked a large, complex NO₂ sterilizer for the pharmaceutical and medical device market. These exclusive licenses are for all power free applications for:

1. The developing world; royalty 5%
2. Global for disaster relief and emergency response; royalty 7%
3. Global for militaries; royalty 7%
4. Global for Veterinary market; royalty 10%

The company has filed for patent on its gas generation module.

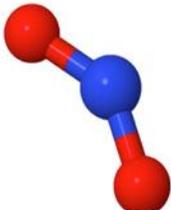
The Licensed NO₂ Technology

The nitrogen dioxide (NO₂) technology kills bacteria, viruses and spores at room temperature and has been successfully commercialized, FDA cleared and CE marked for use in the pharmaceutical and medical device markets.

Eniware has adapted this cutting edge technology in its EPS-25 portable sterilizer and is the only company in the world that can effectively sterilize surgical instruments in low-resource healthcare settings without electricity at room temperature.

NO₂ sterilization works at room temperature without any power required. It can sterilize surgical instruments as well as basic medical supplies in a short period of time. A portable, small-scale sterilization chamber and patent pending simple mechanism to generate and release NO₂ will enable health care workers to safely sterilize vital instruments anywhere at any time. Moreover, the manufacture of the EPS 25 is scalable. The simplicity of the concept provides for minimal training requirements, widespread use, expanded access to safe and effective sterilization, and function at the point of care.

Benefits of the EPS-25

NITROGEN DIOXIDE (NO₂)

Molecular weight: 46 g/mol
Boiling point: 21 °C (70 °F)
Gas density: 3.4 kg/m ³
UN Number: UN1067
Description: Yellowish-brown liquid or reddish-brown gas with a pungent, acrid odor.
Most Resistant Organism: Geobacillus stearothermophilus
5-minute EEL (emergency exposure limit): 35 ppm; 15- minute EEL: 25 ppm
IATA Regulations: modified Jan 1, 2017 to allow for air transport via passenger cargo



The components of the EPS-25:

- The sterilizer case is a 25 liter off-the shelf, machined Pelican Case with custom gaskets, safety latch and load stabilizer
- The controller bezel that regulates the cycle times, directs the user and actuates safety locks when the cycle is active.
- The gas generation/scrubber housing and assembly that holds the gas generation ampoule, triggers the release of NO₂, and houses and controls the scrubber function.
- A locking system that prevents the case from being opened while the sterilization cycle is running.
- A set of consumables required for each cycle
 - The Sterilnox Kit contains:
 - A gas generation ampoule,
 - A scrubber and
 - A neutralizer for safe disposal of the gas ampoule on completion of the cycle
- Supplies required
 - An enzymatic cleaner powder to be used in a bucket/tub of plain water to reduce the bacterial load on the materials to be sterilized (Redukt™)
 - A set of three stainless steel trays to organize and hold surgical instruments
 - Chemical indicator strips that change color in the presence of the sterility gas that are placed in the EPS 25 for each cycle to confirm gas release. (CI's)

SterilNox™ Kit & EPS trays



The EPS is easy to operate. After properly preparing and placing instruments in the trays and placing in the case, the cover is closed and latched. A scrubber and gas generation ampoule are inserted. The cap is placed and depressed to activate the sterility gas release. The bezel screen displays directive and confirming messages. When sterilization is complete (2 hours), the scrubber is activated. Upon completion of scrubbing (2 hours), the case may be opened at anytime thereafter and the instruments placed on the sterile field. The bezel functions are powered by three C batteries, which last for over 100 cycles and are easily replaced.

Nitrogen dioxide is a well-studied gas being a principal constituent of smog. It functions at room temperature and offers broad material compatibility including most reusable medical equipment. It is dramatically safer than similar sterilant gases such as hydrogen peroxide and ethylene oxide. It is effective against bacteria, viruses, and spores. Use of NO₂ gas for sterilization translates into rapid aeration leaving no residue at the end of the cycle.

4. COMPANY OVERVIEW

Eniware pronounced “anywhere” was founded in 2011, by James Bernstein, MD and Huma Malik. Eniware LLC has exclusively licensed, and is adapting a unique NO₂ technology for low-resource environments including disaster response, humanitarian crisis, veterinary markets, militaries worldwide and developing countries. The result is a portable, power-independent, room temperature and cost-effective surgical instrument sterilization device. The NO₂ technology is commercialized in the US, Japan and Europe and is CE marked, EPA and FDA approved.

Eniware is on the WHO compendium list for 2014.

http://www.who.int/medical_devices/innovation/compendium/en/ (2014 page 34) and was the finalist on Fast Company 2018 World Changing Ideas Award <https://www.fastcompany.com/40546728/the-2018-world-changing-ideas-awards-finalists> (Under Health)

Dr. Bernstein and Huma Malik have invested in the company both with sweat equity and investment, working for the last 6 years with minimal, sporadic compensation. They are both committed to the mission of Eniware and have been active participants in the voice of the customer, travelling to 4 African countries in conjunction with Jhpiego.

Eniware is headquartered at 7920 Norfolk Avenue, Bethesda, Maryland. The Company uses an outside accounting firm, JFW Accounting Services LLC, until such time as a full-time CFO becomes necessary. The company maintains its accounts with Bank of America. Legal services are provided by Pillsbury Shaw Pittman, LLP. Eniware’s manufacturing is located in Baltimore, MD at Harbor Designs &

Manufacturing. HD&M helps their clients realize the full potential of their innovative ideas or core technology. Their cutting edge and diverse manufacturing processes enable their experts to create products on time and within budget.

KEY COLLABORATORS

Eniware has collaborated with:

1. **Jhpiego**: Has been a collaborator since our early days. Worked with us to carry out the 5 country Voice of the Customer/Feasibility studies in East Africa.
2. **Johns Hopkins Medical School**: We have been helping each other for several years. We have collaborated with them in several areas. They are part of an MOU we have with Pro Health International in Nigeria. Dr Sampson led the team, which introduced our EPS-25 in Freetown, Sierra Leone June 2018.
3. **International Medical Group**, Uganda. We have collaborated with them for several years. They will be purchasing the EPS-25 for their hospitals and clinics when it is CE-marked. In addition they have made themselves available for any ease-of use beta testing we may need in the future.
4. **Samaritan's Purse**, We are in discussions and will be meeting next month with their team in North Carolina to demonstrate and test the finished EPS-25. They will be using it in their disaster relief and humanitarian activities.
5. **Phillips**, We have on going discussions with them and are awaiting our CE mark to test the EPS-25 in their solar powered primary health centers in sub Saharan Africa in collaboration with their innovation center in Nairobi.
6. **Harbor Designs and Engineering**: Our design, engineering and contract-manufacturing partner has invested part of their fees in Eniware.
7. **Agalloco Associates**: Our sterilization validation partner has invested part of their fees in Eniware.

5. BUSINESS PROPOSTION

Value Proposition:

The cost to individuals, employers and governments from lack of access to essential surgery is estimated as high as 30% of the total disease burden. Much of these costs are "amenable" to simple solutions including the availability of sterilizers.

Providing power-free sterilization technologies to LMIC countries will permit health practitioners to engage in safe surgical practice and behavior. These activities can lead to a measurable reduction in surgical site infection and medical device (masks, catheters) related infections with an attendant reduction in the cost of care. These savings can free up scarce resources for other vital priorities and will lead to a reduction in Disability Adjusted Life Years (DALYs) which in turn should add to economic capacity. Moreover, the EPS assembly and local manufacture can create a local value chain and extend far beyond its immediate function.

The Business Model.



With a very large addressable market, Eniware will make haste carefully and deliberately, listening to the market and learning from our initial deployment. No matter where or through what channel, the basic model is based on a one-time sale of an EPS-25 (and subsequent versions) and the continuing revenue stream from its use with each batch of instruments sterilized constituting a “cycle.” For detailed information on forecasts see section 9. Financial Projections.

The business grows additively as a function of the installed base. This effect coupled with a decreasing operating expense (decreased cost of sale, sales by distributors) leads to robust cash flow and profitability determined by how fast the company can place sterilizer units.

Since its inception the company has paid close attention to all of the elements required to achieve scale. These include:

- Identifying and developing a strong “bench” of future team members.
- Executing a strong, diverse communication strategy to inform and persuade key stakeholders including articles, TV appearances, social media, speaking engagements, and lectures
- Forging close collaborative relationships across universities, NGO’s, medical schools around the world. The company has long standing collaborations with Jhpiego, Johns Hopkins Medical School and International Medical Group in Uganda as examples.
- Building relationships with government officials, diplomats and important influencers to provide support for future activities. As an example, the company currently is engaging the new government of Ethiopia to explore local manufacture and distribution within Ethiopia (100 million people).
- Building a business model and launch plan that assures sufficient cash flow and profitability to grow into the developing market efficiently including technology evolution, space, external resources.
- Creating an institutional knowledge base and capability that ensures continued excellence in all aspects of the business while rolling out a tested product and its support systems.
- Pursuing all actions and steps that can stimulate market growth and uptake of our products. For example, Eniware was instrumental in the launch of the G4 Alliance, which has become a force internationally promoting safe surgery. Eniware is also on the WHO compendium list for 2014. http://www.who.int/medical_devices/innovation/compendium/en/ (2014 page 34)

In the short term the company will focus on ramping up manufacture, pushing down the cost of goods through volume sales and adding key staff members to support training, logistics and financial management. Positive cash flow from sales should occur within the next 12 months when the company has at least 150 Units installed in the developing world. This excludes capital expenditures for manufacture ramp up.

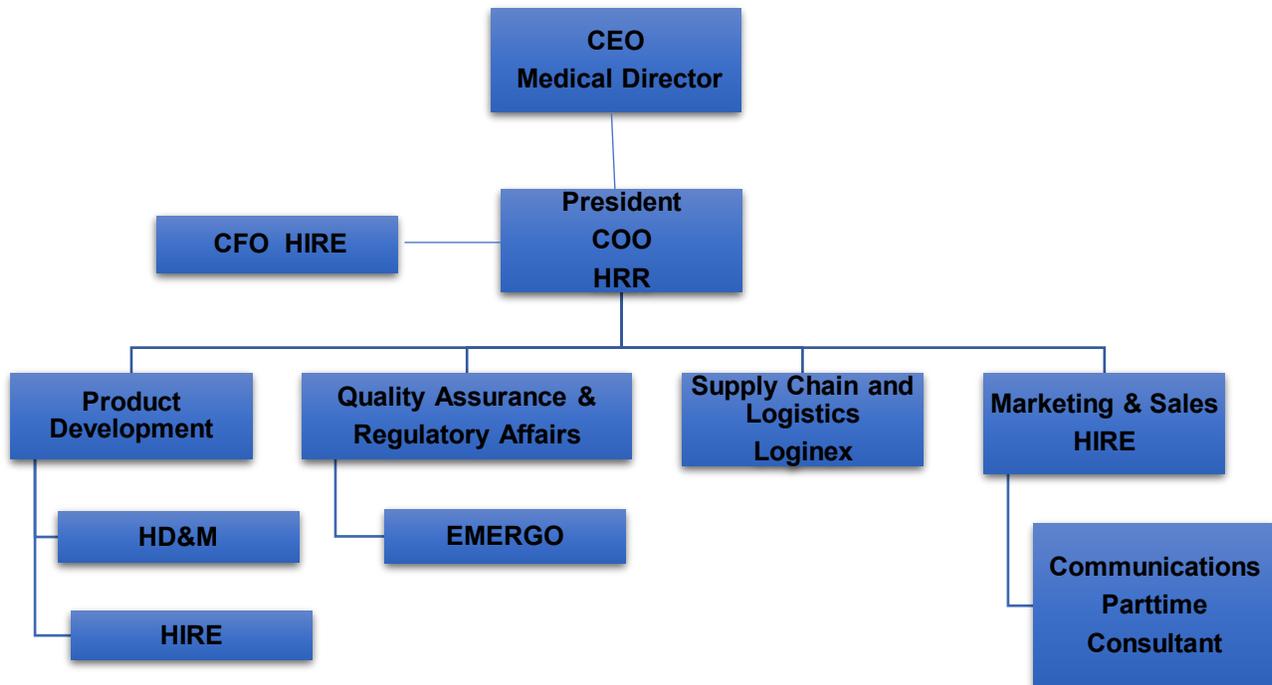
An important part of our initial market launch is a distribution company in Uganda, The Essential Surgery Company LTD, owned 49% by Eniware, LLC. Chaired and directed by Dr Ian Clarke, Chairman of Uganda Healthcare Federation and East Africa Healthcare Federation who also serves on the Eniware Board, this give the company unparalleled access to and local knowledge of the Sub Saharan market.

6. MANAGEMENT TEAM

Eniware’s management team is comprised of seasoned executives and entrepreneurs with experience in health care, medical technology, international development manufacturing, logistics and public-private partnerships. The organization is structured to function efficiently and to leverage the expertise of key

advisors and consultants providing the Company with interdisciplinary breadth and depth needed to develop the Eniware technology.

The Organizational Chart



James Bernstein, M.D.
 Chairman & CEO, Eniware

Dr. Bernstein is the Co-Founder and CEO of Eniware LLC. Prior to starting Eniware, Dr. Bernstein founded and served as CEO and Chair of the Board for Noxilizer, Inc. The significance of Eniware’s mission and the product’s potential impact have been highlighted by Forbes and Medical Dealer Magazines. Dr. Bernstein was Chief of Staff of the Chairman of the Board of Supervisors of San Diego County and while in that job was responsible for the introduction of gasoline vapor recovery for the first time in the U.S., which is now regulation throughout the U.S. and the E.U. He also served as Deputy Director of the Georgetown University Health Policy Center, headed up the efforts to ensure ongoing physician competence at NIH, and chaired President Carter’s health policy advisory group during his first campaign for President. Dr. Bernstein has an extensive and impressive record as a healthcare entrepreneur. He has been involved in the founding and leadership of numerous companies that have seen commercial success and made significant contributions to the healthcare marketplace. Notably, Dr. Bernstein took his bioinformatics start-up InforMax public in 2000, raising \$80 million. Since founding Eniware, Dr. Bernstein has become a vocal advocate for increased access to safe essential surgery around the world, and is a frequent speaker at international academic conferences devoted to global surgery. Recent speaking engagements include the University of Utah’s Center for Global Surgery Annual Conference, and the World Congress of Surgery, Obstetrics, Trauma, and Anesthesia. Dr. Bernstein is a graduate of Harvard College and Cornell University Medical School, and is trained in thoracic, vascular, and transplantation surgery. He was also a senior researcher in the laboratory of Jonas Salk -- who developed the first polio vaccine -- and assistant to the President of the Salk Institute.

Huma Malik
President, Eniware

Huma Malik has more than twenty four years of experience in the non-profit sector with a proven track record of working effectively in a diverse environment demonstrating political sensitivity, the ability to manage complex social, political and cultural issues, and deliver clear balanced analysis and council. 8 years ago, Ms. Malik made a dramatic change of direction. She took a deep breath and committed herself to doing what she “must” not what she “should”, a person committed to improving the well being of people around the world. And thus began her dynamic career as an entrepreneur teaming up with an experienced entrepreneur to launch her current venture, Eniware. Ms. Malik has experienced the well-chronicled emotional roller coaster ride while acquiring an impressive armamentarium of business skills from marketing and sales to six sigma voice of the customer product design and development to the intricacies of human resource management, finance and scaling. Prior to this part of her life journey, Ms. Malik had extensive experience in project development, finance and public relations at CSIS and Georgetown University covering a range of political and development issues, including democratization, gender issues, and human rights. At CSIS, Ms. Malik oversaw the prestigious group of international Counsellors chaired by Dr. Henry Kissinger She has experience in cross cultural issues, vocational training, and conflict resolution workshops and seminars including conducting field training seminars in Bosnia and Croatia. Ms. Malik is co-editor of Modernization, Democratization and Islam (CSIS, 2005) which addressed the themes of education, international economic and trading systems, development and gender roles, and the role of the military in Muslim majority countries, Islam and Human Rights (July 2005) as well as Integrating Muslim Communities in Europe and the United States: A Transatlantic Dialogue (CSIS, 2003). At Georgetown University, Ms. Malik oversaw a successful transition of the ACMCU Center from an academic institution to foreign policy-oriented think tank, managing a \$20 million grant. Ms. Malik served as Vice President for Finance and Development at the Woman's National Democratic Club. She was the recipient of the Award of distinction for outstanding service from the School of Foreign Service, Georgetown University.

Ms. Malik also has extensive experience in cross cultural issues and vocational training, having worked in the Sultanate of Oman during the implementation of the “Omanization Policy” geared at improving the local worker percentages over foreign workers in 1988. No stranger to risk, Ms. Malik is a certified scuba dive instructor and an avid skydiver and kayaker.

OUT SOURCED

Agalloco & Associates- James Agalloco

Since the formation of Agalloco & Associates in 1991, Dr. Agalloco has assisted more than 200 healthcare firms in a wide range of validation, aseptic processing, sterilization, and compliance areas. Jim has over 45 years of industry experience. He has authored or co-authored more than 40 book chapters, over 110 papers and lectured extensively on sterilization, aseptic processing and process validation for PDA, ISPE, PhRMA, and other organizations, domestically and internationally.

HD&M - Kevin Barnes, President

HD&M helps their clients realize the full potential of their innovative ideas or core technology. Their cutting edge and diverse manufacturing processes enable their experts to create products on time and within budget. Their priority is developing the best product possible. They leverage both local and international contacts to produce products and closely oversee the entire process to guarantee a high quality and low cost result.

Emergo

Emergo helps medical device manufacturers strategically leverage their existing regulatory approvals so they can enter new markets quickly and cost effectively. Hiring an experienced consultant with a global view and local expertise is critical. While they cannot control how fast Ministries of Health review registration applications, they do everything they can to get us in line for approval as quickly as possible.

Loginex International

Loginex is recognized as the preeminent provider of global logistics services to and throughout the developing world. Our decades of comprehensive experience and success operating on time and on budget are unparalleled. Loginex brings evolutionary progress to the world's most critical supply chains.

Board of Directors

James Bernstein, M.D.

Chairman & CEO, Eniware

Ian Clarke, MBChB BAO, DTM&H, MSc

Founder, Executive Chairman, International Medical Group

Dr. Clarke is a physician, missionary, philanthropist, entrepreneur, and politician in Uganda, the third-largest economy in the East African Community. He is the former Mayor of Makindye Division, one of the five administrative units of Kampala Capital City Authority. He enjoyed a landmark victory and was sworn into office as Mayor of Makindye Division in May 2011 to serve for a five-year term. He is also the Chairman of the Ugandan Healthcare Federation and East Africa Healthcare Federation. Dr. Clarke is the founder and Chairman of International Medical Group (IMG), the largest private healthcare organization in Uganda, encompassing a 100-bed hospital, medical insurance company, a non-profit foundation, and a network of primary care clinics. Ciel Healthcare Limited recently acquired a majority shareholding in IMG. Dr. Clarke also owns Clarke Group, which has interests in education (including International Health Science University and a school), hospitality (apartments, hotel, and restaurant), and agribusiness (trees, coffee, maize, and chickens). Dr. Clarke is the author of three books – *The Man with the Key Has Gone*, *How Deep is This Pothole*, and *Smart Culture Guide to Uganda*. He writes a weekly social commentary for the Sunday Vision Newspaper.

Jeffrey Leonard, Ph.D.(deceased, Oct 15, 2018)

President and CEO, Global Environment Fund

Treasurer, New America

Dr. Leonard is the president and CEO of Global Environment Fund (GEF), one of the most experienced and most successful private equity firms dedicated exclusively to investments in the energy and environment sectors. Founded in 1990, GEF currently has approximately \$1 billion in aggregate capital under management. Dr. Leonard served as chairman of the Board of Directors of the Emerging Markets Private Equity Association (“EMPEA”) from 2011-2015 and also has previously served as co-chairman of the Clean Technology Venture Network. From 2006-2007, Dr. Leonard served as co-chairman of the energy transition team of Maryland Governor Martin O’Malley. Dr. Leonard is a founding board member of the National Council for Science and the Environment (NCSE), Chairman of the Board of City Year (Washington, D.C.) and Chairman of the Board of The Washington Monthly. He is a founding board member and Chairman Emeritus of the Board of Beacon House Community Ministry, a not-for-profit organization dedicated to improving the lives of children and their families in northeast Washington, D.C. Dr. Leonard is a graduate of Princeton (Ph.D.), London School of Economics (M.S. Economics) and Harvard College (B.A., magna cum laude). He is the author of five books and numerous technical articles

relating to global environmental issues, international trade, energy production and technology development.

Terry Lierman

Founding Partner, Summit Global Ventures LLC

Mr. Lierman has served clients within both private and public sectors across core industries including health, energy and education with over 30 years of consulting and communications experience. Mr. Lierman has provided a variety of organizations with media-relations advisement, communications management, business sustainability, and program administration. He is currently the founding partner of Summit Global Ventures LLC, where he consults and invests in promising health, medical device, and energy-related companies. He has also played integral roles in the business development and patient education of health information technology for organizations like eNeura Corporation and CSGI.

Knowledgeable on legislative program development and initiatives, Mr. Lierman worked as Chief of Staff to both the Democratic Whip and the Majority Leader of the U.S. House of Representatives. During that time, he oversaw and directed various duties and responsibilities within the office, including management of staff, policy and floor initiatives and directives. Serving as White House liaison, Mr. Lierman provided fundraising oversight, political direction and coordination between multiple groups. Mr. Lierman also stood as the Maryland Democratic Party State Chair, responsible for developing and managing statewide communications and fundraising operations. Prior to being a State Chairman, Mr. Lierman displayed his health development and program administration skills in executive positions at Health Ventures, TheraCom, and Employee Health Programs as he consulted on business plans, feasibility and public relations. Mr. Lierman has served on multiple boards and community service organizations including Advocacy Institute, Alliance for Eye and Vision Research, Business Leader for Sensible Priorities, and Children's Research Institute. Mr. Lierman earned a master's degree in public policy and administration from the University of Wisconsin and a bachelor's degree in political science from Winona State University.

Huma Malik

President, Eniware

Michael Steele

CEO, Steele Group Inc.

Mr. Steele was elected Lieutenant Governor of Maryland in 2003, becoming the first African-American elected to statewide office and again with his subsequent chairmanship in the Republican National Committee (RNC) in 2009. Under Mr. Steele's leadership, the RNC broke all prior fundraising records and in 2010, the Republican Party picked up the greatest number of seats in the House of Representatives since 1938. In 2012, Mr. Steele co-founded Purple Nation Solutions, Inc., public relations and strategic-communications firm, with former White House Counsel Lanny Davis, and Emmy award-winning media & communications professional Eleanor McManus. Mr. Steele is a regular commentator and political analyst for MSNBC and has served as a contributor on the Fox News Channel. He is a graduate of Johns Hopkins University and the Georgetown Law Center.

ADVISORS

Eniware has assembled a group of experienced professionals who are leaders in their disciplines to advise and assist the Company in its goal of developing and successfully introducing a portable sterilizer.

Rifat Atun, MBBS, MBA, DIC, FRCGP, FFPH, FRCP

Founder, Executive Chairman, International Medical Group

Dr. Atun is Professor of Global Health Systems at Harvard University, where he is the Director of Global Health Systems Cluster at Harvard University's School of Public Health. From 2006 to 2013, Dr. Atun was Professor of International Health Management and Head of the Health Management Group at Imperial College London. He is an honorary professor at the London School of Hygiene and Tropical Medicine. Dr. Atun has worked extensively with the World Bank, World Health Organization, and the U.K. Department for International Development on design, implementation, and evaluation of health system reform programs in more than 20 countries.

Elizabeth Birch

Elizabeth Birch has had an extensive career that spans the corporate, legal, public policy, and nonprofit worlds. From heading litigation at Apple Computer, Inc. to playing a critical role in advancing LGBT rights at the helm of the Human Rights Campaign, Birch is known for her ability to lead teams to extraordinary achievement. Included in her extensive client list are: American Airlines, McDonald's, IBM, Intel, Cisco, General Mills, Google, Nationwide, Deloitte, U.S. Department of Defense, U.S. Navy, Mass Mutual, Visa, Cardinal Health, and Kaiser Permanente.

Laura S. L. Herman, MBA, MA

Ms. Herman has over 15 years of strategy consulting experience and leads FSG's global health practice area. Her clients include non-profit organizations, private foundations, and corporations with a focus on strategy, program design, evaluation, market analyses, and stakeholder engagement. She holds an MBA with a certificate in Public Management from Stanford's Graduate School of Business. She also holds an MA in International Policy from Stanford University and a BBA in International Business from the University of Michigan.

Jack Levine, DDS

Dr. Levine has a private dental practice in New Haven, CT, and has also been working with dentists in the developing world for the last twenty years. He is a Fellow in the International College of Dentists, the American College of Dentists, The Academy of General Dentists, and the Pierre Fauchard Academy. His travels for dentistry have taken him to Nepal, Peru, Jamaica, Uganda, Rwanda, Tanzania, Kenya. He is currently the Program Director for the Health Volunteers Overseas dental project in Haiti. Dr. Levine received his Doctor of Dental Surgery degree from Temple University School of Dentistry and studied at the L.D. Pankey Institute for Advanced Dental Education.

Donald MacDonald, MD

Dr. MacDonald is an ophthalmologist at MonMouth Eye care in New Jersey. He has performed not only thousands of LASIK and PRK surgeries over the last 15 years, but also over 10,000 cataract surgeries over the past 25 years. As part of Right to Sight and Health, he has participated in many humanitarian missions to the Philippines, Nicaragua, Ghana, Cameroon, Rwanda, Senegal, and Tanzania, restoring vision to thousands of blind people who have no access to health care, as well as performing many eye plastic surgeries. He completed his residency at the Manhattan Eye, Ear, Nose and Throat Hospital and his Fellowship in Eye Plastic and Reconstructive Surgery at both the New York Eye and Ear Infirmary and the Manhattan Eye, Ear, Nose and Throat Hospital.

7. MARKET OVERVIEW/ENTRY STRATEGY

Eniware has exclusive licenses for power-free applications of the breakthrough NO₂ sterilization technology for:

- The developing world
- Central and South America
- Militaries world-wide
- Global disaster relief and Emergency response
- Veterinary use world wide

A brief overview of these markets follows:

1. The developing world
 - a. Detailed data is scarce but the World Bank, Who and the UN are all in agreement that there are critical shortages of infrastructure and tools for good surgical care.
 - b. The Lancet Commission estimates that there are ~150 million surgical procedures that should be done on an annual basis with over 90% in the developing word.
 - c. Adequate essential surgery is defined as 5,000 surgeries /100,000 population. (Lancet Commission, World Bank)
 - d. Up to 30% of the burden of diseases amenable (avoidable) with essential surgery.

-In 2010 an estimated 16.9 million (33%) of all deaths globally were lost from conditions needing surgery.

-77 million disability -adjusted life years (DALY's) could be avoided with basic essential surgery every year.

-Access estimates;

- 93% in SSA do not have access to safe, timely, affordable surgery
- 97% in South Asia do not have access

-C-section rate was .1-1% in East African countries compared to over 15% in developed countries

-Almost 1 million women do not have access to emergency obstetrical care

Exhibit 1 Countries' estimated age-standardized amenable mortality rate per 1,000 people in 2015, by country, scaled by quintile



- e. 60% of the population of sub Saharan Africa is off the grid.
- f. Two procedures, voluntary male medical circumcision (VMMC) and Caesarean section alone comprise 30 million procedures per year. (These conditions fall into the "amenable" conditions for essential surgery
- g. Customers are in both the public sector and private delivery groups and centers. Payment may come direct from the user or from funds coming from donor institutions (World Bank, EU, DFID, UNICEF; Gates Foundation and other Foundations) and through NGO's funded by USAID and others.
- h. The company has a substantial backlog in East Africa which can become orders as soon as regulatory approval has been obtained later in 2018

- i. Other applications in the developing world, which have been recently brought to our attention, include sterilization of microbiology diagnostic glassware in remote laboratories (FHI360) and hospitals that belong to the Green Hospital Initiative. 4,000 hospitals worldwide. (FHI 360)
 - j. The company has forecast fewer than 20,000 EPS-25 Units by the end of 2021 with the related revenue from consumables from 4 million cycles.
2. Mission trips
- a. There are numerous missionary groups who travel to developing world locations to perform surgery for a number of weeks. There has been robust demand from this group for the EPS-25 as well as surgical instrument sets to be left behind and then subsidized by the sponsoring organization. There is no competitive solution for this group.
 - b. The company estimates 100 such EPS units placed by the end of 2021 generating revenue from 50,000 cycles
3. Disaster relief organizations
- a. The number of natural disasters per year has been increasing each year. These disasters often require a large coordinated response from designated organizations such as Samaritans Purse. There are over thirty such organizations. The company has been in contact with several, all of whom have expressed serious interest in having the EPS-25.
 - b. The company has forecast a very conservative number of units since it has no direct experience to date. However, There are five key players in the post-emergency market – these five organizations make up 38% of the market: and spent \$2.8 billion in 2010.
 - Médecins Sans Frontières
 - Catholic Relief Services
 - Oxfam International
 - International Save the Children Alliance
 - World Vision International
 - c. According to History, Trend, Forecast (HTF) report, “the Global Emergency Medical Service (EMS) Products Market is accounted for \$19.16 billion in 2017 and is expected to reach \$35.95 billion by 2026 growing at a CAGR of 7.12% during the forecast period. The incident and emergency management market is driven by many factors, such as rising terrorist and biohazardous attacks, increasing incidents of natural disasters, stringent government regulations and norms, and a need to avoid the huge monetary losses due to disasters.”
 - d. Eniware is critical to natural disasters (no electricity) but also to terrorist attacks where on the spot triage is becoming more urgent and mobile units need portable sterilization. These disasters often require a large coordinated response from designated organizations such as Samaritans Purse. There are over thirty such organizations. The company has been in contact with several, all of whom have expressed serious interest in having the EPS-25.

Eniware’s go-to-market strategy involves engaging with the leading emergency response organizations, including those listed above as well as Samaritan’s Purse, ICRC, IRC, and other relief organizations, to furnish portable, electricity-free Eniware kits in disaster zones.

- 4. Refugee camps
 - a. There are over 25 million refugees worldwide. Growing at 44,000 per day.

- b. Healthcare in refugee camps has an unmet need for basic safe simple surgery (C-sections for example) based in part due to lack of electricity.
 - c. The company has not forecast any sales here but will be making a concerted effort to begin to service in this market upon receipt of funding.
5. Militaries
- a. The company has interacted with medical staff from several countries outside the US as well as several parts of the US armed forces (SOCOM for example).
 - b. The EPS-25 has been greatly admired, but the company has not had the resources to pursue military contracts. No revenue has been forecast for this segment but should be substantial, as the EPS becomes more widely known.
 - c. FDA approval will be required for US military which the company will pursue next year.

The global surgery market grows rapidly in part because of the laser focus of WHO, the World Bank and the rapid rise of Universal Health Coverage in the emerging markets.

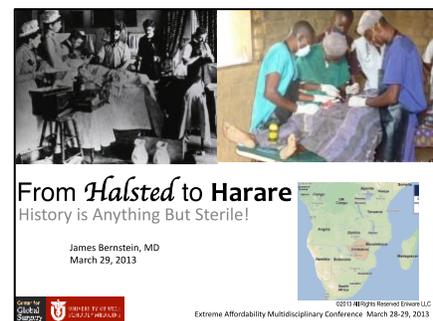
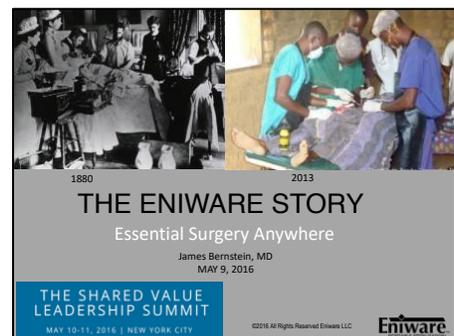
The value proposition, cost benefit analysis and sales approach is quite similar to all. The reason - everyone who operates in electricity short environments that does basic triage to essential surgery immediately understands the EPS-25.

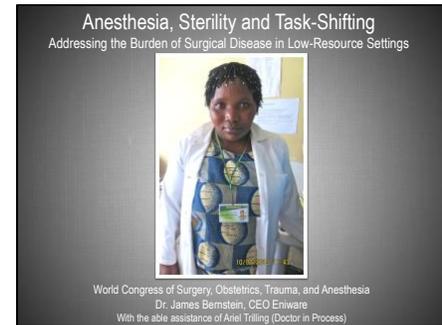
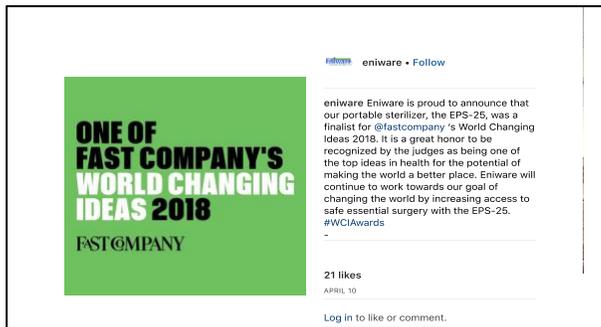
MARKETING AND SALES

Eniware will sell its product line through local in-country distributors, and direct to institutional buyers such as NGOs, disaster relief organizations and militaries.

The company has built awareness and interest in the EPS-25 since the company's launch with a vigorous communications/PR program which has included:

1. Articles in public and professional media including, for example, the Huffington Post, Forbes, PLOS, Cornell Alumnae Magazine. See Appendix.
2. TV appearances on FOX and ABC Channel 8, (DC)
3. Presentations in public forums including a TED talk and key note at the Shared Value Summit in 2016
4. Presentations and lectures in academic settings including medical schools, engineering schools, business schools.
5. Social media including Instagram, Linked-In, Facebook.
6. Presentations at conferences and exhibitions





The company will sell through a variety of channels. The basic sales message is simple: “Eniware is the only portable sterilizer that does not need electricity, heat or water.” If that is the customer’s need, the benefit is obvious. Concomitant features of safety, material compatibility and ease of use reinforce the sale. Pricing models will be tailored by experience and by market segment. Initial margins may be lower to facilitate technology by acceptance and market penetration.

- Wholesale through local in-country distributors. Experience has shown that local knowledge and networks are critical to product acceptance and market growth. The company has partnered in an East Africa distribution company, the Essential Surgery Company, LTD in Uganda (TESCO). They will create and meet demand, provide training and technical support. Eniware will ship from Baltimore, get paid in US Dollars by the local distributor. TESCO will identify and negotiate distributorships throughout East and possibly West Africa.
- NGOs such as Jhpiego, PSI, FHI 360 who purchase through their government and donor contracts. An NGO that provides Voluntary medical male circumcision will purchase the EPS-25 and use it in their provision of services. (Confirmed through direct conversations with NGOs.
- Retail direct by Eniware to:
 - Disaster relief organizations such as Samaritans Purse,
 - Mission trips
 - Customers where the company has not yet established local distribution
 - The Veterinary market in the US until such time as the company has identified appropriate wholesalers or to organizations such as ASPCA spay-neuter mobile clinics.
 - Military contracts

After sale services will include:

- Training provided by Eniware to its distribution partners after which they will be responsible
- Maintenance
 - Periodic gasket replacement by distributor
 - Fan replacement if necessary
 - Other minor situations
- Warranty: The company will replace malfunctioning EPS-25 during the warranty period to be determined

8. BARRIERS TO ENTRY/COMPETITION

Eniware’s portable sterilization units compete with and complement existing disinfection and sterilization solutions in the developing world, military/disaster/refugee relief, and veterinary markets. However, the Eniware unit also has the potential to dramatically expand access to sterilization in environments where no solution currently exists, while offering improved material compatibility over autoclaves. Here we address existing competitors while keeping in mind that these sterilization products have not effectively penetrated the vast and ever-growing market for sterilization in resource limited environments. The EPS-25 is different from anything in the field:

"The people of Uganda need this solution urgently."
-Ugandan Ambassador to the U.S., Oliver Wonehka

	Cost per unit/per cycle	Weight	Required Supplies	Power Use	User Friendliness	Material Compatibility
AUTOCLAVE	\$8000-10,000/unit	40-100 lbs.	Continuous supply of distilled water	24 kw	Easily damaged, often must be monitored throughout cycle, requires highly trained technician for repair	Degrades heat sensitive materials, cannot sterilize disposable instruments or prefilled syringes
EPS	~\$2500 per unit ~\$20/cycle	~5 kg or 11 lbs.	SterilNox™ Kit and CI	None	Simple, user-friendly designed to withstand any environment. Maintenance free	Broad material compatibility, of devices, supplies and packaging-including plastics

EPS vs. Autoclaves: A Comparison

Autoclaves

First invented in 1879, the autoclave relies on a combination of heat, pressure, and steam to sterilize contents. While highly effective, autoclaves require water, an abundant energy source, and can degrade sensitive instruments or devices. Autoclaves range in price from a few hundred dollars to tens of thousands of dollars.

“Stovetop” autoclaves are an electricity free alternative to the traditional autoclave, but require significant fuel (wood) inputs in the developing world. Typical heat sources include small, dedicated gas stoves and/or wood fires, which are commonly used for cooking. In some cases, disposable items like latex gloves are autoclaved and re-used. These autoclaves typically cost \$200-\$400, weigh 20 lbs., and are limited to stainless steel instruments.

The US military use the “Portable Steam Sterilizer,” self-described as “Big Bertha” for the US military. This general purpose military field sterilizer has been manufactured by ETC continuously since 1969. The autoclaves can weigh over 500 lbs., and have an initial cost of approximately \$27,000, consumes 9

kilowatts of electricity and 5-gallons of water per cycle, occupies a 60.2 ft. cube, and cannot be used on plastics.



Boiling



Solar Autoclave



Steam



Steam- Military

Chemical Sterilants and Disinfectants

According to the U.S. Army, common liquid chemical disinfectants and gas sterilants either do not work well in the field (cold rinses of Cidrex or peroxyacetic acid) or are too hazardous (ethylene oxide) to be transported safely. More broadly, bleach is commonly used in disinfection of medical equipment and surfaces. However, it does not achieve sterilization.

While there are clearly established companies in the developed world low-temperature market and in the more limited developing world autoclave market, they are vulnerable on four fronts:

Benefits:



Cost-Effective
\$2500 per unit
\$20 per consumables
needed for each cycle

Power-independent
Requires no electricity or
other fuel source to
operate

Portable
Enables essential mobility
for remote healthcare
delivery

Better Material
Compatibility
Room temperature-Allows
for re-use of instruments
and supplies

Throughout East Africa, the need for the EPS-25 is reflected in the across-the-board reports of broken autoclaves, and autoclaves that cannot be run because of regular electricity outages. Dr. Badru from the Kibuli Islamic Hospital in Uganda was explicit about this when he said, “we need to move beyond autoclaves.” The major medical distributors, like Joint Medical Stores, MEDS (With access to their distribution channels in Uganda, DRC, South Sudan, Rwanda, and Tanzania) and Critical Care are keen to distribute the EPS-25, which one of their employees described as, “needed everywhere.”

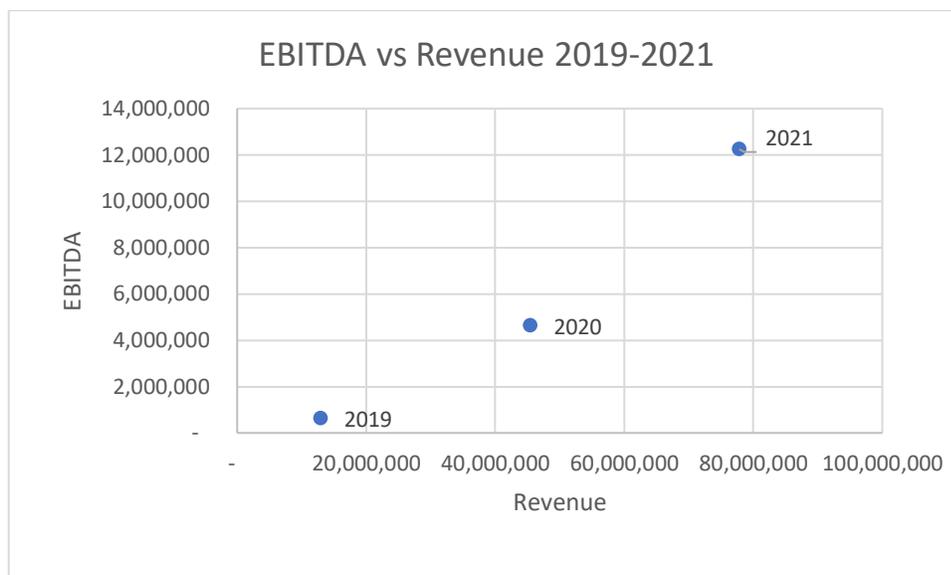
“From the point of view of IMG, (Uganda, pvt.) we have 17 stand alone clinics and a one hundred bed hospital. Both the clinics and the hospital have power, but sterilization is still an issue, not because of the power, but because autoclaves break down all the time. We installed a new autoclave in IHK five years ago at a cost of \$70,000 and we are now getting a new one because we will not pass our COSHASA accreditation with the current sterilisation facilities. Now, if the EPS was available we would put them into all the clinics and the hospital, because the solution of having a surgical set in a box, ready to pick off the shelf to carry out a Caesarian Section or a laparotomy is a no brainer.” Dr. Ian Clarke, Chairman IMG, Uganda

9. FINANCIAL PROJECTIONS

The company forecasts strong revenue and EBITDA growth.

The information shown below are PRO FORMA forecasts based on financing secured by the fourth quarter of 2018, 2018. Because this offering will not close until January 2019, the Pro Forma forecasts should be adjusted forward by 90 days. These estimates are based on the company’s assumptions about market acceptance as well as COGS and operating expenses.

Revenue and EBITDA are shown in the chart below



This forecast is based on a number of assumptions most of which have been tested and validated by extensive market research. The revenue model is built on the number of EPS Units that are sold and the resulting recurring annual purchase of consumables with each EPS Unit.

This sales assumption by market segment is shown below.

	2018	2019	2020	2021
Site Forecast by Segment	Sites			
Healthcare				
Developing world	50	1,500	5,000	9,000
Missions	2	50	75	100
Disaster relief/refugee	1	20	50	50
Military				
Veterinary	2	100	200	500
CUMULATIVE EPS SITES	55	1,670	5,325	9,650
CUMULATIVE EPS UNITS*	114	3,300	10,650	18,700
EPS UNITS SOLD	114	3,186	7,350	8,050

The consumable revenue forecast derives from the above forecast and is based on a set of use assumptions, which include:

A developing world site will purchase on average 2 EPS sterilizers. Each EPS will be used an assumed number of times per year. Each use is a cycle.

The forecasted number of cycles by segment is shown below.

ENIWARE				
Cycle Sales Forecast by Segment				
	2018	2019	2020	2021
Healthcare	# of cycles			
Developing world	5,000	501,250	2,037,500	4,300,000
Missions	112	16,800	38,125	53,125
Disaster relief	5,600	6,629	280,000	280,000
Military	not forecasted but likely			
Veterinary	50	8,263	23,125	54,375
TOTAL	10,762	532,942	2,378,750	4,687,500

EBITDA and REVENUE are driven by pricing (margins). Assumptions reflect the split between wholesale and retail sales as well as market segment. Developing world will be more price sensitive than disaster relief or military. The chart below shows these assumptions as well as cost of goods estimates. The cost of manufacture changes quite dramatically with volume. The company has been focused on getting consumable manufacture cost down. It is clear that manufacture out of the US will be much less expensive. The company is currently exploring a potential arrangement in Ethiopia.

	2018	2019	2020	2021
ENIWARE				
EPS Units Sales	114	3,186	7,350	8,050
wholesale revenue	114,000	4,248,000	11,025,000	12,075,000
retail revenue	68,400	1,593,000	2,450,000	2,683,333
Total EPS revenue	182,400	5,841,000	13,475,000	14,758,333
# cycles	10,762	532,942	2,378,750	4,687,500
wholesale revenue	82,329	5,293,887	26,582,531	52,382,813
retail revenue	46,815	1,878,619	5,431,479	10,703,125
Total Cons. Revenue	129,144	7,172,507	32,014,010	63,085,938
TOTAL REVENUE	311,544	13,013,507	45,489,010	77,844,271
TOTAL COGS	202,787	7,582,769	26,974,688	46,721,875
Gross Margin	108,758	5,430,738	18,514,323	31,122,396
	34.9%	41.7%	40.7%	40.0%
Assumptions				
Cost/EPs	\$ 1,000	\$ 1,000	\$ 900	\$ 800
Cost per cycle	\$ 8.25	\$ 8.25	\$ 8.25	\$ 8.25
Sales Channel				
% Wholesale-distributor	70%	80%	90%	90%
% Retail-Direct by Eniware	30%	20%	10%	10%
Gross margin wholesale	30%	40%	40%	40%
Gross margin retail	50%	60%	70%	70%

Operating expenses are estimated as shown in the summary pro forma P&L

ENIWARE					
3.25 year Pro Forma P&L					
		(\$\$\$)			
		4mos. 2018	2019	2020	2021
Revenue		311,544	13,013,507	45,489,010	77,844,271
COGS*		202,787	7,582,769	26,974,688	46,721,875
GROSS MARGIN		108,758	5,430,738	18,514,323	31,122,396
G&A		250,000	1,301,351	3,639,121	4,670,656
Marketing		28,039	780,810	2,274,451	3,892,214
Sales**		63,232	2,062,621	7,056,181	9,341,313
R&D		250,000	650,675	909,780	973,053
TOTAL		591,271	4,795,457	13,879,533	18,877,236
EBITDA(loss)		(482,513)	635,281	4,634,790	12,245,160
% of revenue			5%	10%	16%
Assumptions					
G&A		na	10%	8%	6%
Marketing		9%	6%	5%	5%
Sales*		15%	12%	12%	12%
R&D		80%	5%	2%	1.3%
*Note: COGS includes 25% distribution (wholesale) cost					
** Note: includes discounts, promotions, royalties					

10. INVESTMENT OVERVIEW

The Company is offering investors up to \$1,000,000 in equity or debt and is open to structure.

Eniware seeks up to \$1,000,000 to fund:

1. Completion of our regulatory filings for CE mark
 - a. Upgrade our ISO certification
 - b. Prepare and submit the standardized “technical file” for the CE Mark
2. Scaling up manufacture
 - a. Enter into supply agreements with our principal vendors
 - i. Acid Products for the gas generation module
 - ii. Sorbco for the scrubbers
 - iii. Crosstex for the CI’s
 - iv. Haemosol for the REDUKT powder
 - v. Miltex/Integra for surgical instruments if necessary
 - vi. Aesculap for closed cases
3. Closing sales from existing backlog
 - a. The company will focus on large opportunities in the developing world and in disaster relief to close initial orders and generate cash flow.
4. Finalizing distributor relationships
 - a. Work with The Essential Surgery Company as needed
5. Accelerating marketing efforts
 - a. Attending conferences
 - b. Making high level sales calls

The Use of Proceeds for the next 6 months is shown in the table below.

General Operations*	\$	300,000.00
Regulatory	\$	195,000.00
Training	\$	25,000.00
Manufacturing ramp up	\$	295,000.00
Shipping/Packaging	\$	45,000.00
Launch/marketing	\$	80,000.00
Accts payable reduction	\$	50,000.00
Total	\$	990,000.00

*Includes marketing

To date the company has raised \$4.7 million dollars that have been spent as shown in the below table.

	2012	2013	2014	2015	2016	2017*	TOTAL
Investment Received	\$465,001	\$407,500	\$290,000	\$2,000,050	\$214,950	\$450,000	\$3,827,501
Non -functional model for VOC	62,000						62,000
Voice of the Customer. Feasibility	75,000						75,000
Technology development*	6,000	20,000	80,000	213,000	108,000	15,000	442,000
Design, Engineering, Manufacturability**			20,000	410,000	305,000	70,000	805,000
Market Development/customer development	120,000	128,000	48,500	27,000	15,000	9,000	347,500
Product components, casting "tools"	40,000		31,000	36,000	313,000	20,000	440,000
G&A***	170,000	360,000	637,000	381,000	227,000	225,000	2,000,000
TOTAL	473,000	508,000	816,500	1,067,000	968,000	339,000	4,171,500
* In house expenditures							
** includes outside collaborators, consultants							
*** includes license fees							

In addition to invested capital, the senior management has worked from the inception of the company for only small and sporadic draws and has written off over \$1,000,000 of accrued compensation.

The Company's Capital Structure:

The Company has three classes of Units all of which are bound by the LLC Operating Agreement.

1. Class A Units: 1,800,000 Authorized, 120,859 remaining in Treasury
2. Class A-1 Units: 100,000 Authorized; 69,937 Remaining. Have broad based anti-dilution protection at \$22.00/Unit
3. Class B Restricted profit share units: 300,000 Authorized; 72,198 remaining.

Class A	594,294
Class A-1	30,063
Class B	227,802
Warrants A	15,500
Warrants A-1	21,000
TOTAL FULLY DILUTED	888,659

The Cap Table as of July 2018

11. EXIT STRATEGY

The most likely scenario will be an acquisition of Eniware at some point in the not too distant future. There is no comparable solution available anywhere and Eniware has a monopoly on power free sterilization. Autoclaves are the only available method of sterilization in hospitals and health centers in the developing world, but they are often broken or inoperable due to a lack of electricity. When working autoclaves are unavailable, health workers must use chemicals or boiling water to disinfect instruments, but disinfection is insufficient for preventing infection during surgical procedures. Therefore, as global sterilization companies look for solutions for essential surgery in LMIC countries we will be on their short list of must have technologies.

The potential acquirers of Eniware will be the big players in the sterilization field like:

- Johnson & Johnson
- General Electric
- Getinge
- Phillips
- Asahi Kasei Corporation
- 3M
- Belimed

12. OTHER RESOURCES NEEDED

Manufacture

- Production lines- The company will have to negotiate and fund large scale orders to bring down the price of key consumables
 - gas generation ampoule
 - scrubber
- Tooling for manufacture of plastic casting

Regulatory

Eniware will continue to follow a formal Product Development Process in compliance with the ISO 13485 and FDA/CE requirements for Good Manufacturing Process. It will be using outside consultants as necessary to complete submissions for CE Mark.

Distribution

The company will need to identify and negotiate distribution agreements on a country by country basis.

Collaborators

The company will continue to build alliances and collaborative relationships with universities, NGOs and strategic institutions.

Staff

Eniware will pay close attention to the critical requirements for staffing as it builds out its go to market strategy and scale team

Building a robust and competent management team and supporting staff:

- Logistics
- Sales
- Training
- CFO

- Develop a powerful communication team, honing our messages building effective advocacy programs and interacting vigorously with our customers.

Appendix

Eniware is on the WHO compendium list for 2014.

http://www.who.int/medical_devices/innovation/compendium/en/ (2014 page 34) and was the finalist on Fast Company 2018 World Changing Ideas Award <https://www.fastcompany.com/40546728/the-2018-world-changing-ideas-awards-finalists> (Under Health)

IATA Changes

The 2017 edition of the *IATA Dangerous Goods Regulations* includes Special Provisions for the Eniware Sterilizers permitting us to ship our nitric acid consumable by commercial air anywhere in the world. Earlier provisions restricted EPS consumables to Cargo flights with limitations on Nitric Acid. This impacted the amount of Nitric acid we could use and the length of the cycle. This is an exciting development and was done on our behalf by the Dangerous Goods Advisory Council due to the critical need for a sterilization solution that is portable and power free.

Selected Articles

There Is More to Women's Health Than Babies: Categorical Funding Fails the Bigger Purpose

Huma Malik *Co-authored by James Bernstein, MD*

[Read Post](#)

When 'Wow!' Is Not Enough

James Bernstein, MD *Co-authored with Michael Steele*

"Wow!"

It's easy to make an instant impression -- relate the importance of a cause, the revolutionary nature of an idea, the dire need met by a new innovation. We are often generous with enthusiastic praise and encouragement because it comes at no cost, figurative...

[Read Post](#)

When the Good Samaritan Does More Harm Than Good

James Bernstein, MD *co-authored by Donald Macdonald, MD./*

Donald Macdonald is an Ophthalmologist at Monmouth Eyecare in New Jersey. As part of Right to Sight and Health, he has participated in many humanitarian missions to the Philippines, Nicaragua, Ghana, Cameroon.

[Read Post](#)

The India Sterilization Tragedy; Highlighting the Need for Better Choices, Safer Procedures

James Bernstein, MD **Co-Authored by Prashant Yadav, PhD**

Earlier this week [13 women died](#) in Chhattisgarh in central India. They died after undergoing sterilization in a high-volume, low-cost "mass production" type campaign commonly termed "surgical camp." The media outrage over this has been astounding both in Indian and Western media. The...

[Read Post](#)

Doing Well by Doing Good

James Bernstein, MD *Co-authored by Huma Malik*

We are just back from three weeks in East Africa, where the need for simple solutions to overwhelming problems related to providing safe essential surgery confronted us wherever we journeyed. Even the untrained eye could recognize the problems that had been repeatedly told to us by doctors and nurses.

[Read Post](#)

Surgery by Non-Surgeons: An Impending Future

James Bernstein, MD *Co-authored by Jenny Gilbertson and Rose Nanyonga*

Jenny Gilbertson received her Bachelor of Science in chemistry and French at Beloit College and her masters in scientific engineering in bioengineering innovation and design from Johns Hopkins University. She currently lives in Norway, where...

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A New Paradigm for Global Health Research: Local Needs, Local Teams

James Bernstein, MD Co-authored with Dr. Brenda D'Mello. A specialist in OBGYN since 1999, Dr. Brenda is currently working as a Technical Advisor at CCBRT, implementing a regional collaborative comprehensive maternal / newborn and disability inclusive capacity building project in Dar es Salaam, Tanzania supporting...

[Read Post](#)

More 3D for US Foreign Policy: Moving Beyond Soft Diplomacy Through Global Health

James Bernstein, MD **Co-authored with Mohamed Abdouh Kabir**

Years ago [a young woman](#), wise beyond her years, advised me that I would be "a lot happier and a lot more successful if [I] were more 3D and less 2D." Taken somewhat aback, I inquired as to the hidden message in this...

[Read Post](#)

Three Recommendations to Foster Development in Africa's Health Markets

James Bernstein, MD Co-authored by Aline Wachner.

Aline Wachner is a PhD candidate at the International Research Network on Social and Economic Empowerment (IRENE/SEE) at Zeppelin University, Germany. Her research has investigated health care social enterprises in Columbia, Mexico, Kenya, and South Africa. She...

[Read Post](#)

Time for New Revolutions in Global Health Care

James Bernstein, MD

Non-communicable diseases, trauma and maternal death have now assumed a significant part of the disease burden in low and middle-income countries (LMICs), yet these issues are only recently gaining a foothold in the global health dialogue, which has previously concentrated on communicable diseases. A significant number of these conditions, including...

Selected Testimonials

Eniware appears poised to be linchpin piece of bringing modern sterilization and its benefits to hundreds of millions of people around the world who today face, at best, the prospects of surgery performed with poorly disinfected instruments.

Devin Thrope, Forbes Magazine

“The Government of Liberia is soon to roll out a new Ebola strategy that is integrated with a strategy for also rebuilding the health care system. Infection control is at the heart of restoring confidence in the system.”

*- Ambassador Deborah Malac
US Ambassador to Liberia*

“If instruments are not disposable, they must be sterilized before being used again. Without adequate sterilization of the instruments, virus transmission can continue and amplify an outbreak.”

*- Preventing and Understanding Ebola
United States Africa Command*

“It’s exciting to see innovative products like this and learn about the impact it could have on a country like Uganda.”

*- Ambassador Scott DeLisi
US Ambassador to Uganda*

“What’s the delay? We need this right away!”

*- Nurse Goretta Musabayiman
Gasiza Health Center, Rwanda*

“I have worked in Central India since 1996 on the prevention and treatment of infectious diseases in first level facilities. Increasingly my focus has been on maternal and neonatal infections and the limited availability of sterile equipment during labor and delivery. The Eniware solution would be hugely helpful at the more than 3,500 first level Primary Health Centers in India that are responsible for the safe care of almost 1 in 7 of the world’s newborns.

*Patricia Hibberd, MD, PhD.
Chair of Global Health
Boston University School of Public Health*

Because the Eniware Portable Sterilizer (EPS) works without water, heat, power or fuel, this state-of-the-art NO2 sterilization technology is uniquely suited to adaptation for low-resource use in disaster areas, conflict zones and hospitals and clinics throughout the developing world.

Jhpiego affirms that we see a significant value and potential in the EPS and are committed to working with Eniware to identify evaluation and research areas that align with Jhpiego’s

programmatic and technical priorities in maternal and child health services and essential surgery to expand its use in resource limited settings.

*Dr. Tigitsu Adamu Ashengo, MD, MPH
Associate Professor of Public Health, St Paul Medical College, Addis Ababa, Ethiopia*

From the point of view of IMG,(Uganda, pvt.) we have [17 stand alone clinics](#) and a [one hundred bed hospital](#). Both the clinics and the hospital have power, but sterilization is still an issue, not because of the power, but because autoclaves break down all the time. We installed a new autoclave in IHK five years ago at a cost of \$70,000 and we are now getting a new one because we will not pass our COSHASA accreditation with the current sterilisation facilities. [Now, if the EPS was available We would put them into all the clinics and the hospital](#), because the solution of having a surgical set in a box, ready to pick off the shelf to carry out a Caesarian Section or a laparotomy is a no brainer

Dr. Ian Clarke, Chairman IMG

RESEARCH ARTICLE

Nitrogen Dioxide Sterilization in Low-Resource Environments: A Feasibility Study

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Abstract

Access to sterilization is a critical need for global healthcare, as it is one of the prerequisites for safe surgical care. Lack of sterilization capability has driven up healthcare infection rates as well as limited access to healthcare, especially in low-resource environments. Sterilization technology has for the most part been static and none of the established sterilization methods has been so far successfully adapted for use in low-resource environments on a large scale. It is evident that healthcare facilities in low-resource settings require reliable, deployable, durable, affordable, easily operable sterilization equipment that can operate independently of scarce resources. Recently commercialized nitrogen dioxide (NO₂) sterilization technology was analyzed and adapted into a form factor suitable for use in low-resource environments. Lab testing was conducted in microbiological testing facilities simulating low-resource environments and in accordance with the requirements of the international sterilization standard ANSI/AAMI/ISO 14937 to assess effectiveness of the device and process. The feasibility of a portable sterilizer based on nitrogen dioxide has been demonstrated, showing that sterilization of medical instruments can occur in a form factor suitable for use in low-resource environments. If developed and deployed, NO₂ sterilization technology will have the twin benefits of reducing healthcare acquired infections and limiting a major constraint for access to surgical care on a global scale. Additional benefits are achieved in reducing costs and biohazard waste generated by current health care initiatives that rely primarily on disposable kits, increasing the effectiveness and outreach of these initiatives.

Introduction

Access to sterilization equipment is necessary to reduce disease transmission from instruments during surgical procedures. Lack of access to sterilization limits access to surgery, contributing to the fact that less than four percent of the world's surgical procedures are performed in countries with limited resources.[1] As a result, there are an estimated five billion people worldwide who do not receive essential surgical care. A recent Lancet commission concluded that in 2010,