# Autostomy

## Automating Ostomy Care

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Company Name :
Autostomy Inc.

Company Address:
320 W 29th St #200,
Baltimore, MD 21211
United States

# Abstract

Autostomy Inc. is a start-up committed to deliver better ostomy care and has developed the Autostomy Ecosystem—a family of products that automate ostomy care and document patient progress.

Through interviews with patients and medical practitioners, our team discovered a major hurdle for precision ostomy care: a system that relies on human resources and capacity for precision in the menial tasks of measuring and cutting ostomy wafers by hand. These aspects of state-of-the-art ostomy care often lead to inaccuracies that compromise patient wellbeing while proving time inefficient. The Autostomy solves these problems by automatically measuring a patient's stoma and cutting the ostomy wafers so that they always fit correctly. The Autostomy automates precision ostomy care, saving time and most importantly, saving lives. Our app mediates communication between the Autostomy device, the patient, and the care provider to assist with long-term patient monitoring and give patients peace of mind that their provider is regularly monitoring their health. The Autostomy device along with our app and proprietary ostomy pouches and wafers constitute the Autostomy Ecosystem.

# Welcome to Autostomy

## One Integrated Ecosystem

### An Open Ecosystem

**For providing smart, convenient ostomy care for patient.**

## Three Products

### Individual Products

**Combining the cutting-edge algorithm, best performance software with the compact and portable Autostomy device**

## Five Years of Experience

### Experienced Team

**Average experience on different disciplines both industrial and academic for team member is over 5 years.**

# Professionals of Autostomy

## Ruixing Liang

CEO /Algorithm & Software

Ruixing Liang is an Electrical and Computer Engineering graduate student at Johns Hopkins University. He founded Renter Inc. in Shenzhen, China to build a platform for university students to freely share and trade personally owned idle items. Renter Inc. received more than 200K USD as funding from Glaxay Holding Inc. Ruixing was also full-time AI-Algorithm engineer at Amazon Web Services where he develop AI-embedded systems from scratch.

## Vishnu Kolal

CTO / Hardware & Manufacturing

Vishnu Kolal is a Robotics Engineering student at Johns Hopkins University with a bachelor's degree in Mechatronics Engineering from Manipal Institute of Technology in India. He has extensive experience in rapid prototyping, CAD design and manufacturing. He has carried out research in the field of medical robotics under the guidance of world-renowned authors such as Dr. Russell H. Taylor. He is enthusiastic about product development in the field of medical robotics and hopes to make a career out of it.

## Joanna Maressa

COO/ Materials & Communications

Joanna Maressa is senior majoring in Materials Science and Engineering with a Biomaterials Concentration at Johns Hopkins University. She has been an undergraduate research assistant for the Searson Group in the Institute for NanoBio Technology since 2018. Her expertise lies in experimental design, scientific presentations, and written communication. She is interested in downstream product development with a focus on optimizing materials and design to best suit customer needs.

# Autostomy & Our Story

## Every 1 in 500 people have a condition that requires Ostomy care. We are committed to automate ostomy care to improve patient's quality of life.

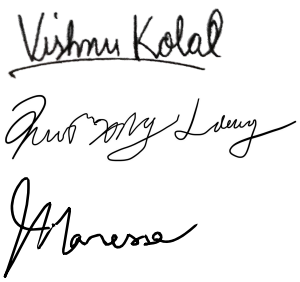
Those who need ostomy care have a condition that requires their intestines to be pulled out of their belly and attached to an ostomy pouch that collects their stools. To attach the pouch, the patient or caretaker needs to measure the circumference of the stoma (opening) and cut a hole in the wafer that connects the pouch and body to fit the stoma. The pouches are designed to stay attached for 2 days, but if they aren't attached properly, then they may fall off within a few hours and bile can leak out. Inaccurate application and leaked bile often leads to skin breakdown and other **medical complications.**

More than **3 million** patients around the globe suffer from conditions that require ostomy care. Many of these patients including those suffering from colorectal cancer and bladder cancer need ostomy care for the **rest of their lives**. This market for ostomy care is strong with an annual growth rate of **3~5 %**.

**We Automate Ostomy Care with the Autostomy Ecosystem.** Our one-of-a-kind tabletop device measures and cuts the hole in the ostomy wafer to make a perfect fit so you don't have to. The Autostomy takes a picture of the stoma, uses a machine-learning algorithm to measure it, and then cuts the wafer, so it perfectly fits every time. Stoma picture data can be transferred to an app that connects patients with their doctors to documenting stoma condition and allow easy monitoring.

We founded Autostomy with the mission to revolutionize ostomy care. Our team is well-equipped to handle the technical and business aspects of this start-up.

Autostomy Inc. Founders:



# Inspired by Desmond's Story and Field Survey

## On Customer Need Research with Ostomy Care Professionals and Customers

Autostomy will be a game changer and saviour for parents who suffer both physically and mentally like I was to care for babies.

-—Alex

This is Desmond. Born at 29 weeks of gestation, Desmond had a slew of medical conditions including necrotizing enterocolitis, which requires ostomy care. After discussing the details of his condition and issues with current state-of-the-art ostomy care with his mother, Alex, we identified major drawbacks that our team could overcome.

Ostomy care involves hand measuring and cutting but requires precision and **time-efficiency which often do not coincide**. We **confirmed these needs** and gained approval for our proposed Autostomy device from Amy Melita, RN and Jeffrey Meyers, MD who practice at University of Rochester's Golisano Children's Hospital in Rochester, New York.

UR MEDICINE
GOLISANO CHILDREN'S HOSPITAL

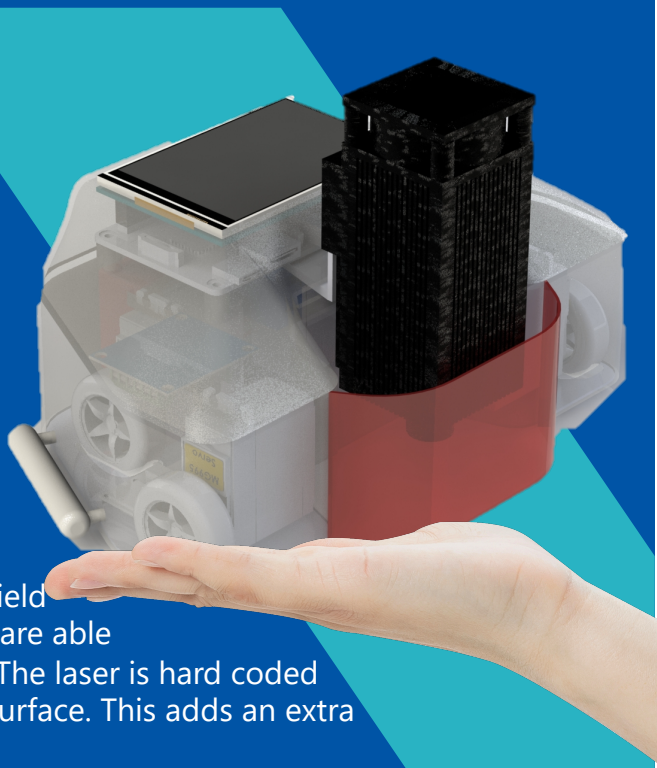
# Intended Use of Autostomy

This product is intended to be used by hospital nurses, ostomy caregivers, and patients who require ostomy care. The Autostomy device was designed with the intention to assist in the measuring and cutting of an ostomy wafer belonging to a two-piece ostomy pouch. The onboard cameras of the device are intended to map the patient's stoma and the onboard laser module is intended to cut the wafer. The device should be operated on a tabletop and is not intended for use by a person who lacks training with general ostomy care and device handling protocol.

The companion app is intended for use by healthcare professionals and patients for the purposes of stoma health tracking. It is only meant to serve as a time series database with some analytics. The app is not intended to substitute the judgement of a trained healthcare professional.

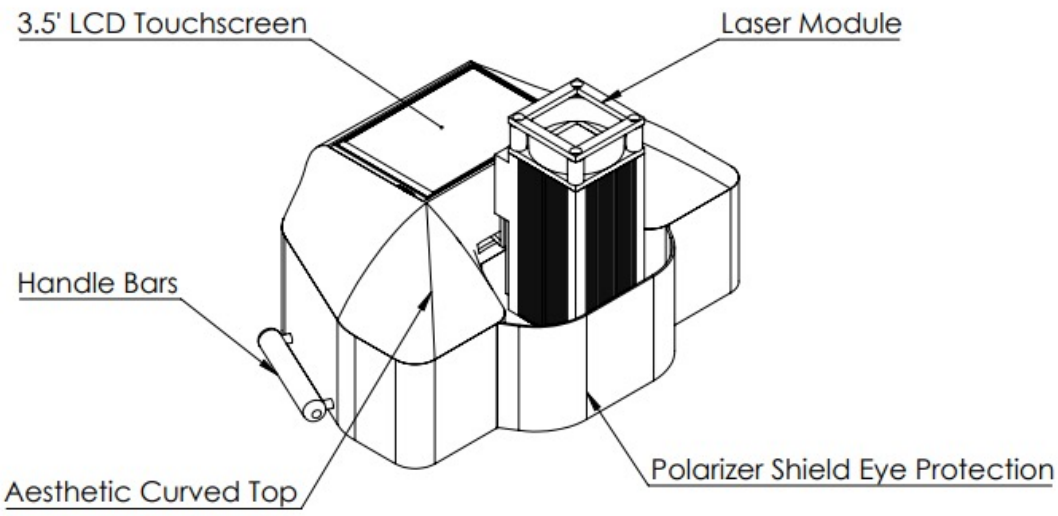
# Meet Next-Gen Ostomy Care: Autostomy.

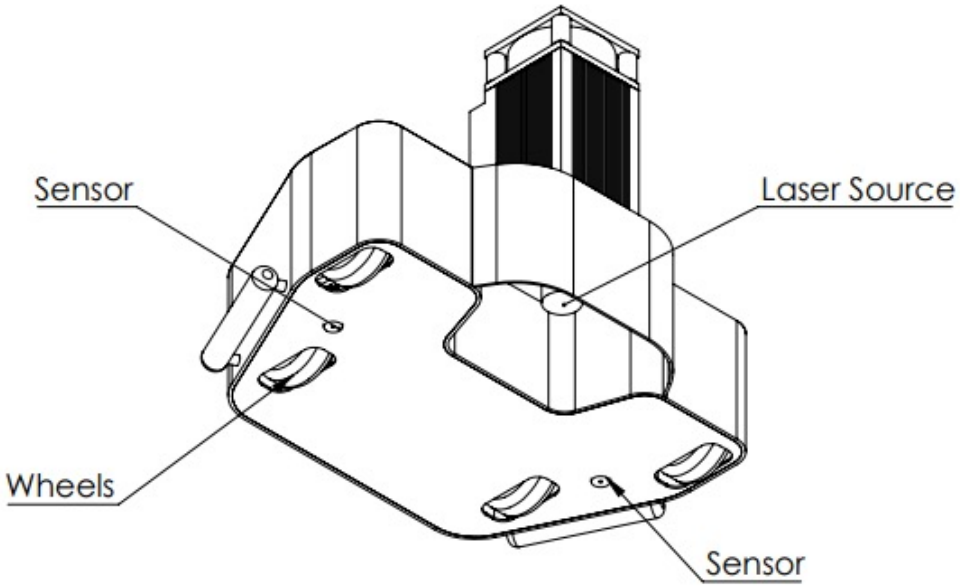
## Scan , Place in front of Autostomy, Press, and Attach Ostomy wafer.



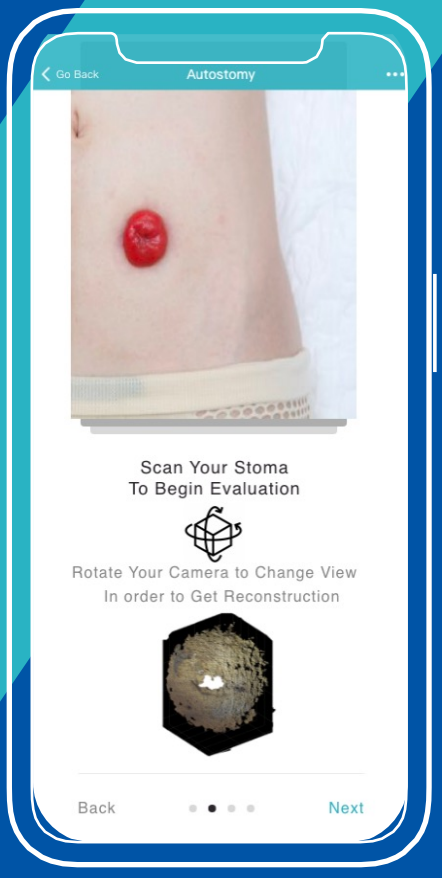
The Autostomy has a curved trapezoidal design which allows for room to mount internal components and effective cooling. The device is designed to be portable hence its small size (20x16cm). It uses a 14W laser module attached to a servo motor to accomplish the cutting task.
The laser is surrounded by a protective polarizer to shield the user's eyes from the laser's radiation. The sensors are able to detect if the device is kept on a flat surface or not. The laser is hard coded to only function when the device is safely on the flat surface. This adds an extra layer of safety.
The device moves on four wheels actuated by servo motors for precise control. The wheels have rubber treads to ensure no-slip performance.
The internals of the device house the driver boards for the motors, the sensors, a 3000 mAhLiPo battery, the Raspberry Pi and necessary connectors to the touchscreen display. The housing itself is made from injection molded white plastic. It comes with two handlebars which the user should hold while scanning.

# Hardware Sketches of Autostomy



# Our Autostomy Mobile App.




## Subscribe to our Documenting Service

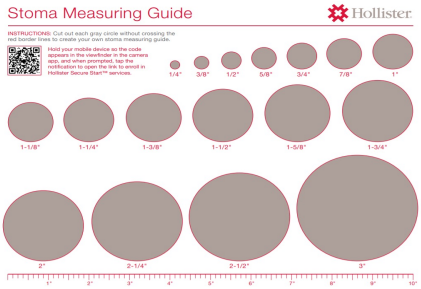
Pictures taken by Autostomy will be sent to the Autostomy Mobile App.* and the patient's provider health care system. This feature enables authorized medical practitioners to check exclusively on patient's stoma to check health status and provide advice if necessary

*: To sync to the user library which is stored either locally or privately on cloud with user authorization each time, specifically on AWS server operated and maintained by Amazon which will be covered more in connectivity rules.

# Algorithm of Autostomy*

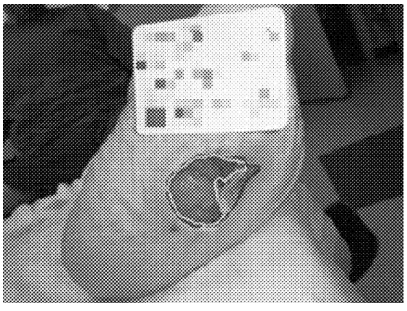
The Autostomy uses a sophisticated algorithm to perform its duties. Generation of a toolpath based on sensor data of the stoma is a challenging feat that cannot be accomplished by traditional image processing or simply applying an AI algorithm.

We estimate the true contour of the stoma instead of trying to approximate a circle to it.



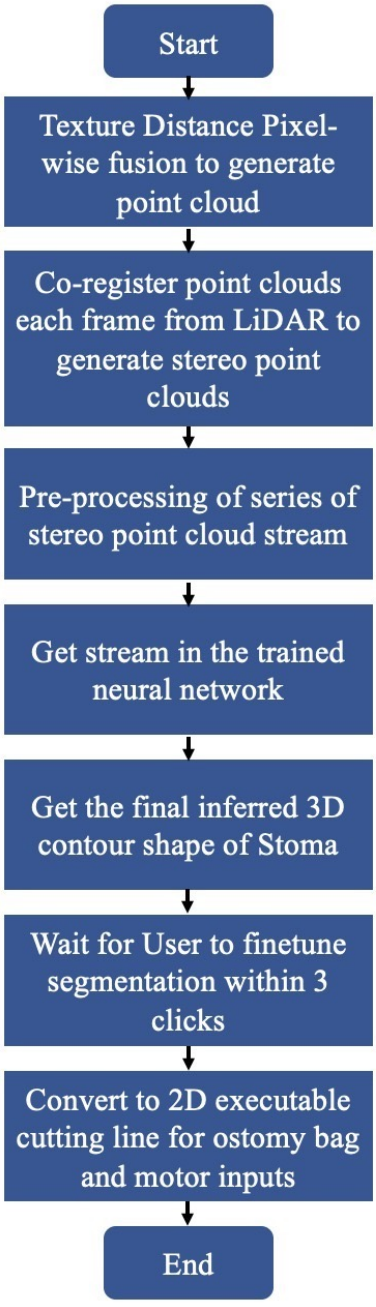

Current approximation involved in ostomy standard practice

With a traditional algorithm on wound analysis, the segmentation is not perfect. Flaws in the output are apparent when comparing the boundary in infra red against the actual boundary. And it could not produce 3D contours even with marker besides wound.



Industry standard algorithm-generated contours

With our algorithm, we're able to achieve the perfect fit. The intermediate steps of the algorithm involve segmentation and isolation of the stoma in the sensor view followed by the generation of a point cloud or a 3D model of the stoma by a neural network. The toolpath for the laser is then derived from the 3D model.*

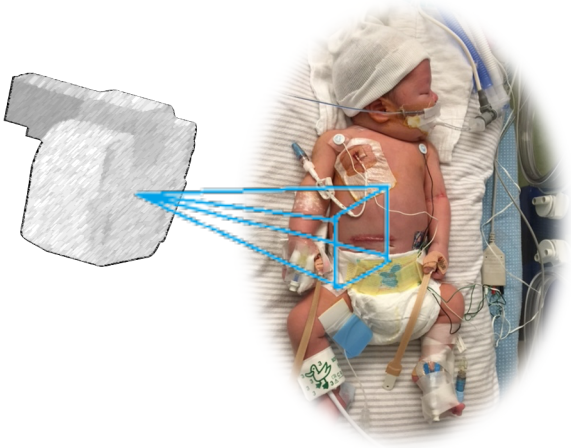



*: For more Details, please refer to Appendix.

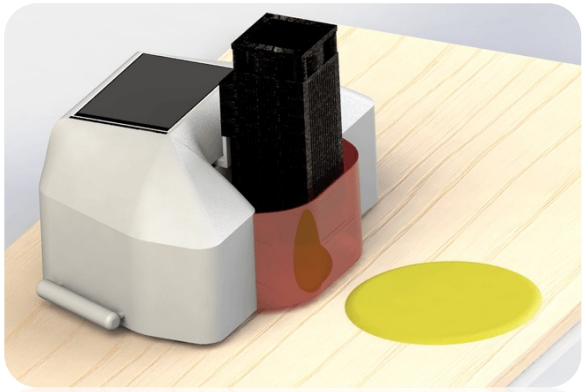
# Autostomy
# Instruction of use

The Autostomy has been designed with commitment to speed and reliability. The instructions for its use are as follows:

1. Power on and lift the Autostomy device using the provided handles to bring the stoma into view of the cameras on the bottom of the device
2. When the “Scan Completed" message appears on the screen, place the device on a flat table
    a. Can edit contours if desire
3. Position the ostomy wafer in front of the device and tap the "Start Cut" button on the screen
4. Once the device has moved away from the wafer, the wafer is customized and ready for use



**1st : Scan**



**2nd : Place on Table**

**3rd : Attach**

# Regulatory, Standards & Connectivity Rules


## Class

Autostomy is a **Class I Device** in Section 876.5900
Ostomy Pouch and Accessories

## Exemption

Section 807.85
Exemption from premarket notification, 510(k)

## HIPPA

PACS system will comply with HIPPA
Rules with AWS support

**Regulatory Information**

Our device is a tool used to customize medical devices that will have physical contact with the ostomy wafer but doesn't come into direct contact with patients. Our final marketable device will causes no harm to the patients and the operators and will be safe and effective. Although we will have to consider biocompatibility of any residue from cutting the ostomy wafer, and any byproducts such as fumes that the device may emit, our final product will take these considerations into account and mitigate any design aspects or biproducts inconsistent with standards and regulations.

**Standards**

The Autostomy will need to comply with air quality requirements at hospitals and health care facilities. Those institutions must comply with the American Society for Heating, Refrigerating, and Air-Conditioning Engineers along with other regulatory standards that address air change rates, humidity requirements, and air pressurization within the buildings. While the intended use of Autostomy does not include altering air quality, we must make sure that any gaseous waste expelled while cutting the ostomy wafers is minimized. We will refer to ASHRAE Standard 62.1, the most referenced standard to meet air quality requirements in hospitals and health care facilities.

The laser is a Class 1 laser and eye protection is recommended although not necessary, especially due the polarizing shield that keeps the laser enclosed.

**Protected Health Information (PHI) Rules**

The HIPAA Security Rule includes addressable implementation specifications for the encryption of PHI in transmission ("in transit") and in storage ("at rest"). Although this is an addressable implementation specification in HIPAA, the AWS in which we will build system requires customers to encrypt PHI stored in or transmitted using HIPAA-eligible services. These actions must be held accordance of guidance from the Secretary of Health and Human Services (HHS).

AWS offers a comprehensive set of features and services to make key management and encryption of PHI easy to manage and simple to audit, including the AWS Key Management Service (AWS KMS). Customers with HIPAA compliance requirements have flexibility in how we meet PHI encryption requirements.

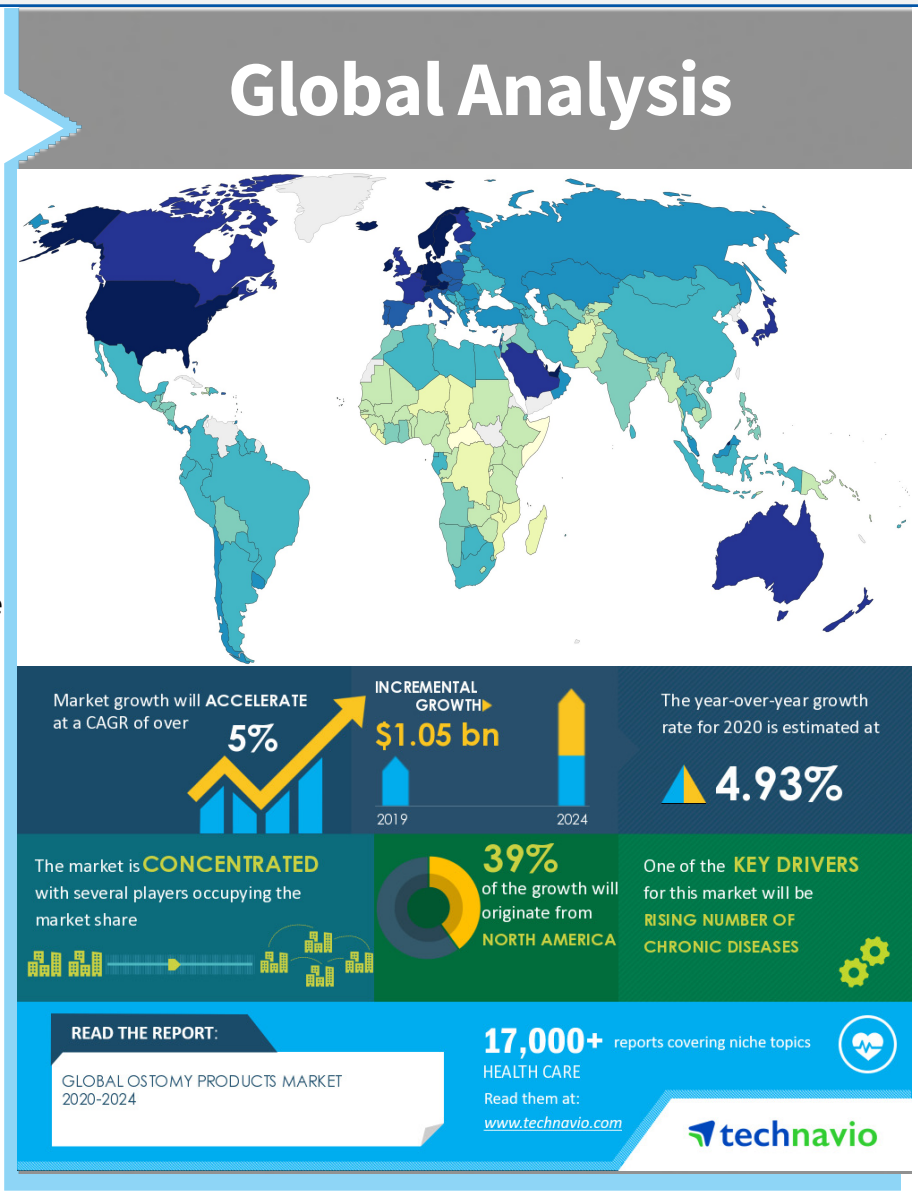
# Autostomy
# Reimbursement Strategy

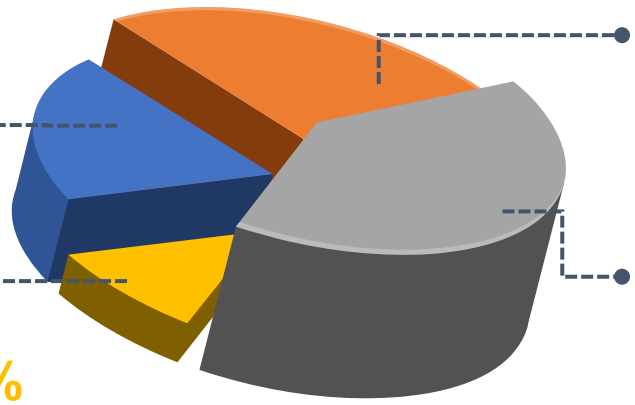
- Patients will be able to be reimbursed for some ostomy pouch expenses with the codes: A4361-A4435 for ostomy pouches and supplies.
- Cost of the Autostomy device may not be reimbursable to patients. Hospitals can pay off expenses by charging patients minimal fees for at-home use.
- We're targeting hospitals and offering rentals with partners so that patients can afford Autostomy.

# Market of Ostomy Care

More than **3 million** patients around the globe suffer from conditions such as colorectal cancer and bladder cancer which require ostomy care. Many of these patients need ostomy care for the rest of their lives. There are**15 million** potential consumers worldwide in total, and the ostomy care market is increasing with annual growth rate varying from **3~5%.**
A positive relationship between economics and ostomy care was observed, and US, Europe, and Australia have the highest prevalence. US as our target market, and specifically, **600 thousand people nationwide have stoma.** 60% of hospitals in the US offer ostomy care and carry out ostomy surgeries.

And We are shocked to find out that these patients need to **pay around $500 each month** simply on the ostomy care accessories itself.



**Urostomy** 16%

A type of urinary diversion, required for many people with **bladder cancer**

**Premature Baby** 2%

Most uses are to treat **necrotizing enterocolitis** of them are temporary not life-long needs

36.8% **Ileostomy**

A type of colonal diversion, some directly caused by **colorectal cancer**

45.2% **Colostomy**

A type of colonal diversion, A consequence of **colorectal cancer** for many

# Competitive Analysis

Companies that provide ostomy care include

- **Hollister Incorporated.**
- **Coloplast Corp.**
- **ConvaTec.**
- Cymed Ostomy Co.
- Marlen Manufacturing & Development Co.
- Nu-Hope Laboratories, Inc.
- Perfect Choice Medical Technologies.
- Schena Ostomy Technologies, Inc.

All have ostomy supplies; none include anything like the Autostomy. Engineers are taught that the best way to avoid a problem is to remove it, rather than take steps to improve its affects. There are some accessories in the market that aim to mitigate negative effects of ostomy products such as stoma powder that helps dry moisture around the stoma, which needn't be there if the ostomy wafer and pouch fit correctly and don't leak. As there are no devices on the market like Autostomy that measure and cut ostomy wafers, products such as stoma powder may provide arguments for potential customers to refusal buying into the Autostomy Ecosystem.

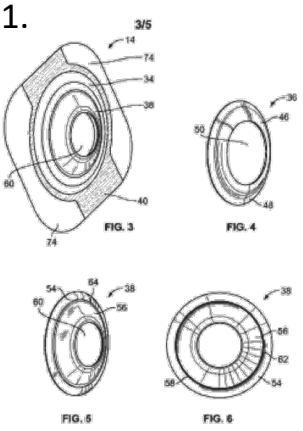
**The main hurdle in making the Autostomy Ecosystem competitive is disrupting the inertia of the current standard of ostomy care.**

# Patent Survey

The patents below are some systems which focus on improving various aspects of ostomy care but do not address the whole system as well as similar algorithms for different uses. So, our system is a completely novel one for application.

1. **Ostomy pouch:** An ostomy pouch with an invertible collar which ideally will seal around the stoma without strangulating it is disclosed in US. Pat. No. 10,512,562An ostomy adhesive
   - The ostomy pouch itself does not provide an AI algorithm and automated method for measuring and cutting
2. Composition comprising a polymer and a switch initiator is disclosed in US. Pat. No. 2017/0239384.*
   - This polymer is used for improving wafer fit with respect to adhesion rather than shape precision.
3. **Algorithm:** An algorithm that automatedly monitoring of the size, area or boundary of chronic wound images is disclosed in US. Pat. No. 2016/0284084.
   - This is only a basic algorithm that has been presented for a different application and is not used within this type of device.
4. **Cut device:** A device that cut with different radius of holes on ostomy is disclosed in FRA. Pat. No. 3 0 15 224.
   - This device is not automated and only cuts circles. It is much less precise than the customization Autostomy provides
5. **System Design:** A system and method for measuring and visualizing a cutting line on ostomy bag by using images taken from phone is disclosed in US. Pat. No. 2020/0337882.
   - While this system involves an algorithm for measuring, it does not include any way of cutting that is included in the system.

1.

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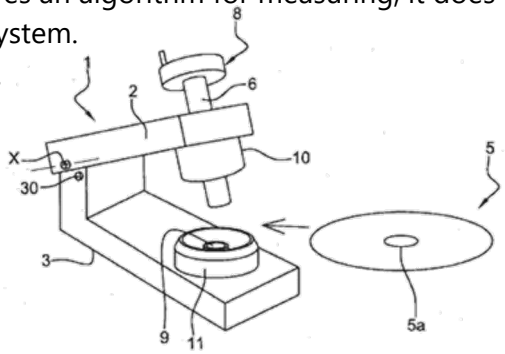


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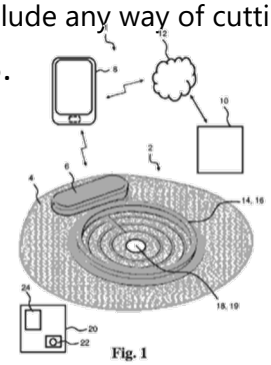


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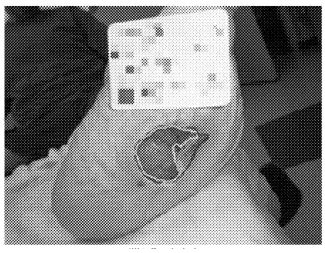
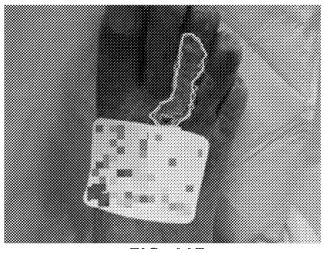




* No image provided

# SWOT Analysis

| | Strengths | Weaknesses |
|---|---|---|
| | ➢ Novel solution<br>➢ Inexpensive product<br>➢ All components easy to procure/manufacture<br>➢ Core team with perfect skillset<br>➢ Have support of nurses and parents | ➢ Not profitable at first<br>➢ Cannot use one piece ostomy pouches<br>➢ No experience with marketing |
| **Opportunities**<br>➢ Expanding market and teletherapy<br>➢ Wound care applications<br>➢ Untapped home use market<br>➢ Large markets in EU and UAE | ➢ Sprint development and fast deployment<br>➢ Rapid prototyping using 3D printers<br>➢ Advertising in hospitals | ➢ Better user experience for long term profit<br>➢ Customer satisfaction by cost saving<br>➢ Hiring marketing firms in each market |
| **Threats**<br>➢ Adoption may be slow<br>➢ Hospitals and doctors may be stuck in their ways<br>➢ Imitation | ➢ Easy GUI for better user experience penetration strategy<br>➢ File patent | ➢ Prototype sharing with key players to pave way<br>➢ Hiring patent lawyers |

Our team has a competitive background for developing this inexpensive and straightforward product. With a promising market, sprint development will allow us to begin an application for FDA approval as soon as possible to quickly be able to penetrate the market. Due to ease of implementation, there is high risk for competitors to adopt similar technology, so we will hastly apply for a provisional patent as well.

To combat limit of profitability in the first phase, we will obtain funds. We will recruit marketing experts to overcome our weakness in that area.

The biggest concern is the inertia of medical practitioners. They will possibly not want to change their current practice.

Details regarding funding, recruitment, and marketing strategy are in subsequent sections.

# Marketing Strategy & Penetration Strategy

## Networking

Build **connections** across academia and industry to maximize the exposure of the products to increase the chance of acceptance.

## Analysis

1. Present to doctors and researchers at **conferences** to convince them to join **product trial** to provide front-line experience of state-of-the-art technology on their fields.

2. **Prototype sharing** with key research hospitals to convince them to **endorse** the new products which revolutionize ostomy care.

## Patient Marketing

**Advertising** in hospitals targeting **directionally** towards potential consumers.

## Analysis

1. Demonstrate the **long-term savings** of using our product as ostomy wafers will be wasted less if cut correctly

2. Use Google Ads or other **intelligent ads distribution** system to deploy ads on targeted consumers with specially designed ads to maximize the possibility to try rent a device to step in our ecosystem.

## Cost Management

Collaborate with government and hospitals with provide funds that **lower** the manufacturer and distribution cost.

## Analysis

1. Based on the huge savings of materials and time in NICU unit. Negotiation between government on allowance and stipend is possible to cover partial costs.

2. Hospital order discount for large quantities to increase our price depreciation ability on unit production cost and even more discount and share for hospitals willing to switch completely on our products in early stage to use our products exclusively.

# 1-Year Business Model

**~After FDA Approval~**

| Sale | Unit sale |
|---|---|
| • Autostomy Device | $ 1,800 |
| • Ostomy Pouch | $ 0.3~2.5 |

Percentage of revenue
**% 86.33**

| Rental | Charge per use |
|---|---|
| • In-Hospital Rental | $ 0.5 Per Use |
| • Take-Home Rental | $ 0.5 Per Use |

Percentage of revenue
**% 10.79**

| App Subscription | Charge per month |
|---|---|
| • Hospital/Medical System Subscription | $ 5 Per Month |
| • Individual Subscription | $10 Per Month |

Percentage of revenue
**% 2.89**

| Product | Count | Cost/unit | Total |
|---|---|---|---|
| Sell Autostomy (Hospitals) | 500 | $1,800/each | $900,000 |
| Rent Autostomy (5,000 people) | 900,000 | $0.50/use | $450,000 |
| Sell ostomy pouches (10,000 people) | 1,800,000 | $0.30-2.50/use | ~$2,700,000 |
| App Subscription | 5,000 | $10/month | $120,000 |

Projected revenue
**4.17M**

# Bills of Material

| PART | COST |
|---|---|
| Laser Module 14W | $200 |
| LiPo Battery 12V 3000mAh | $30 |
| Raspberry Pi | $100 |
| Raspberry Pi Touch Display 3.5in | $45 |
| LiDAR Sensor | $80 |
| Servo Motors x4 | $60 |
| Motor Driver | $10 |
| Wheels x4 | $10 |
| Misc. Wires, Connectors, Fasteners, etc | $50 |
| Housing and Manufacturing | $140 |
| TOTAL | $725 |

# 1-Year Cost Analysis

| PART | COST |
|---|---|
| Salaries | $940,000 |
| Office Space | $54,000 |
| R&D and Rapid Prototyping Equipment | $150,000 |
| Software Licensing | $25,000 |
| Manufacturing First 1000 Units | $700,000 |
| Patent and Legal Fees | $30,000 |
| FDA Application | $6,000 |
| Marketing | $40,000 |
| Distribution | $10,000 |
| Travel Expenses | $15,000 |
| TOTAL + 10% Contingency | $2,100,000 |

# Timeline

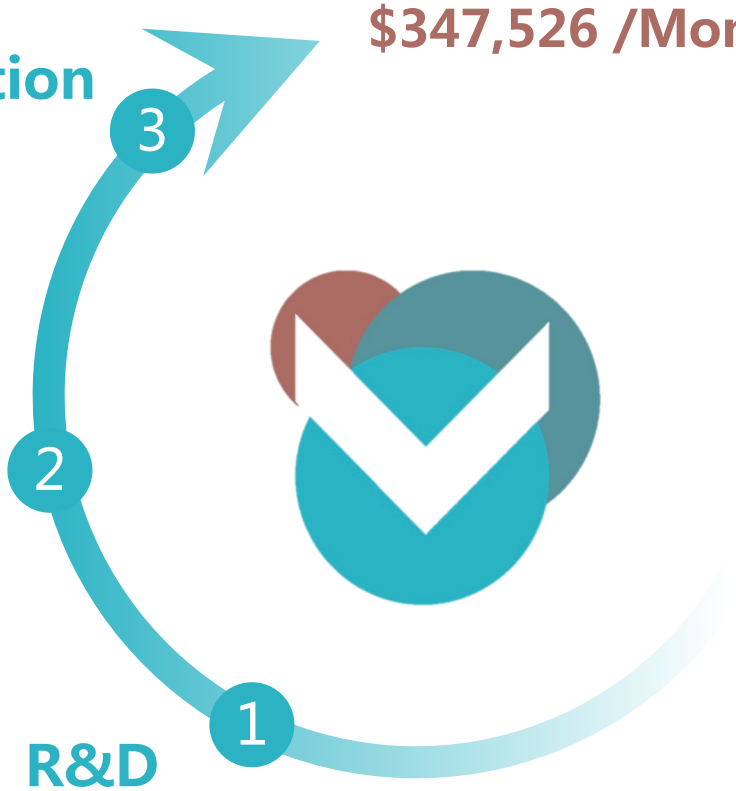
## After Launch, Estimated Profit $347,526 /Month

## Launch & Penetration
**25 Months**

Projected Growth Rate: 5~9%
Cost may expand with scale up company

## FDA Application
**20 months**

FDA Registration: $5,672
R&D Costs Continues




## R&D
**1 year**

Estimated Monthly Costs: 200K

Three stages have been identified. They cover research and development of prototype and proof of concepts which can be further be taken to go through tests for FDA application. During this process, collaboration and prototype sharing will be implemented with acclaimed medical facilities.
After proper penetration of the Autostomy Ecosystem, an explosion of trials of rental Autostomy is projected and with conservative estimation on the profitability of that period of time still reaches to $347,526 per month for a larger scale of company. With the acquisition of market share, profit will significantly increase because the costs will be covered more since the mass usage and production. And still with the conservative estimation, 5~9% of annual growth of profit is projected close to the market increase speed. In ideal case, this figure could be larger exponentially.

# Funding Strategy

Firstly, we plan to use funding from Fast Forward U's incubator and then accelerator funding programs to jumpstart our business. At the same time, we will submit a plan to TCP Venture Capitol, so investors can invest in our early-stage company. We will also submit a project pitch to America's Seed Fund through NSF, and subsequently submit a thorough application.

Kickstarter will be another tool that we use to fund Autostomy Inc. Our Kickstarter strategy will be to propose relatively low-risk mini projects that will fund specific business expenses. These mini projects will only be open for one month, after which we will wait a month before opening another Kickstarter mini project. This strategy will make Kickstarter a way to get small sums of money relatively easily and consistently with little risk.

# Recruitment Strategy

We will immediately hire people to fulfill the following positions: Product Manager, Chief Marketing Officer, Chief Financial Officer, and Business Development Manager.

These positions are critical for the start-up to function fully. Later in the development of our start-up, we will hire: Customer Service Manager, and Sales Manager to. These positions will be advertised on websites such as LinkedIn, Glassdoor, and Handshake to bring well-qualified professionals.

They will be screened for education and prior experience and will go through 2 stages of interviews—a phone interview with the COO, and an in-person interview with the whole team.

# Exit Strategy

There are a few potential ways in which we can exit.

1. Sell our company or attempt to merge with existing established ostomy care providers. Hollister Incorporated, ConvaTec, And Colopalst Corp are the three largest companies that are currently dominating the market. We could propose to merge or sell to them or to sell to the wholly owned subsidiary of Hollister Incorporated: The Firm of John Dickinson Schneider Inc. Once our products are patented, we could also sell our IP and patents to existing ostomy providers.

2. Sell our IP and patents to existing ostomy care providers independently from the company

# Logo Design

The V resembles a sharp, clean scissor signifying the cutting precision Autostomy provides. The color of the circles represents the hope for improving  stoma condition. The successive increase in circle area represents the recursive optimization of segmenting the perfect ostomy wafer and the customization the Autostomy provides.

# Future Development

- Expand the scope of Autostomy to address wound dressings
  - New product called Uwound that works on the same principle as Autostomy, but is tailor made for burn victims and other kinds of surface wounds. It will be able to map the surface of the wounds and cut out dressings to perfectly match the contours and provide good adhesion without wrinkles to prevent unnecessary scarring and accelarate healing.
  - Wound evaluation
- Usage of smart phones and other portable devices equipped with lidar camera for scanning stoma instead of onboard camera

# Thank you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