BAKS Medical

IMPLEMENTING INNOVATION | 10.07.2024

Purpose Statement

WHAT

"We pioneer portable life saving auto-transfusion capabilities that seamlessly recover, and restore patient blood, ensuring stable, equitable access when it counts—wherever it's needed."

HOW

"We pioneer portable life saving auto-transfusion capabilities that ***seamlessly recover, and restore patient blood,*** ensuring stable, equitable access when it counts—wherever it's needed."

WHY

"We pioneer portable life saving auto-transfusion capabilities that seamlessly recover, and restore patient blood, ***ensuring stable, equitable access when it counts—wherever it's needed."***

A pattern of saving lives

This reflects on BAKS and the problem solving ideology instilled by our founders from inception. Leading the way in developing new products that save lives.

Our mission

We at BAKS are dedicated to aiding and speeding up the recovery process for bleeding patients. Ensuring caregivers and patients have the tools needed to succeed regardless of the environment.

Championing

The products BAKS is looking to develop now and in the future ensure consistency, minimal effort and access to technology that is dynamic in its areas of operation. Stability in global health care system.

Introducing BEVEL

BAKS Medical has a bold vision to launch BEVEL, a game-changing autotransfusion device...

But right now, we need regulatory approval.

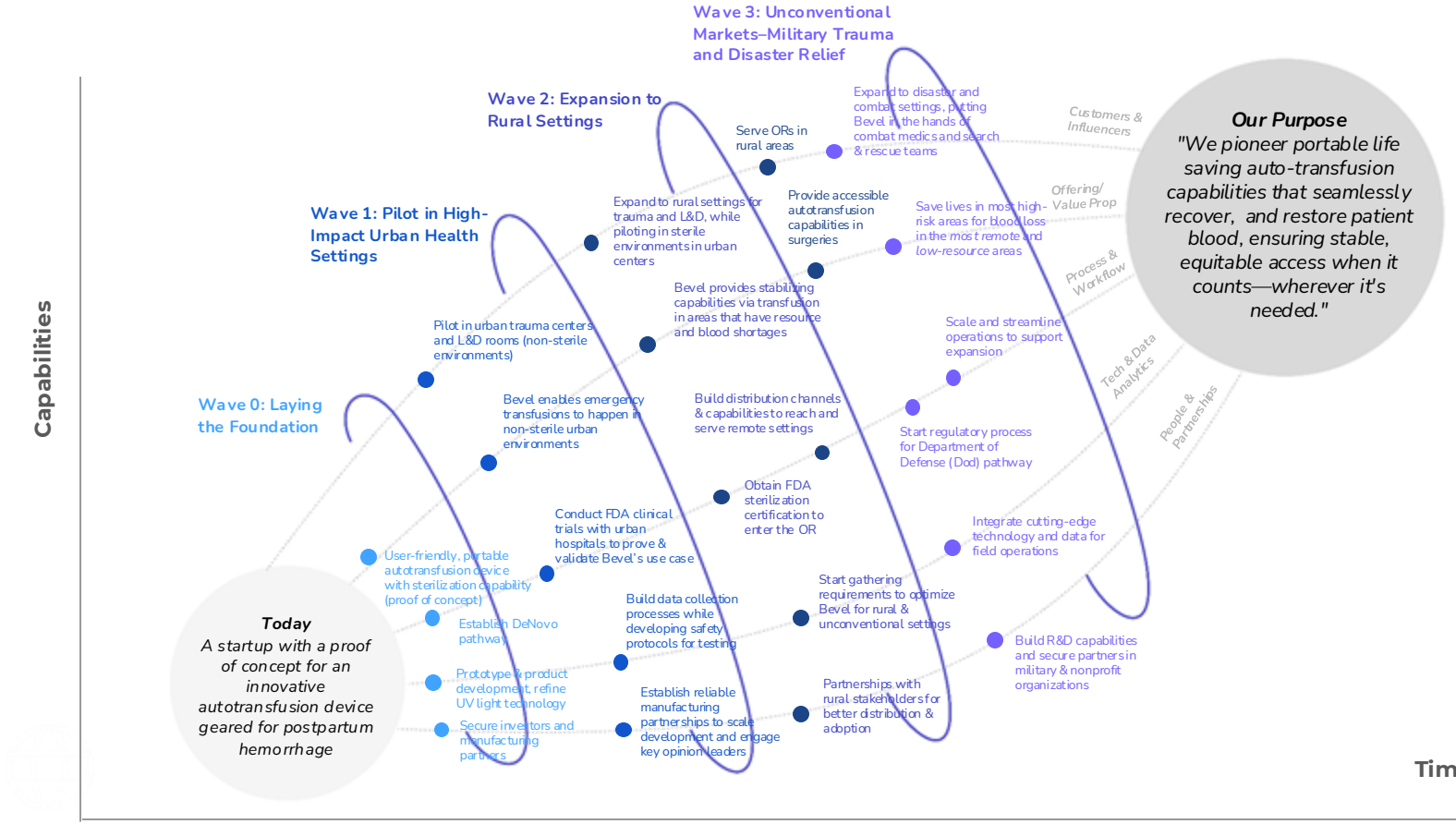
Our prototype still needs to evolve from "looks-like" to a final testable version.

We require partners, data, and funding to bring BEVEL to life.

Competitor Overview

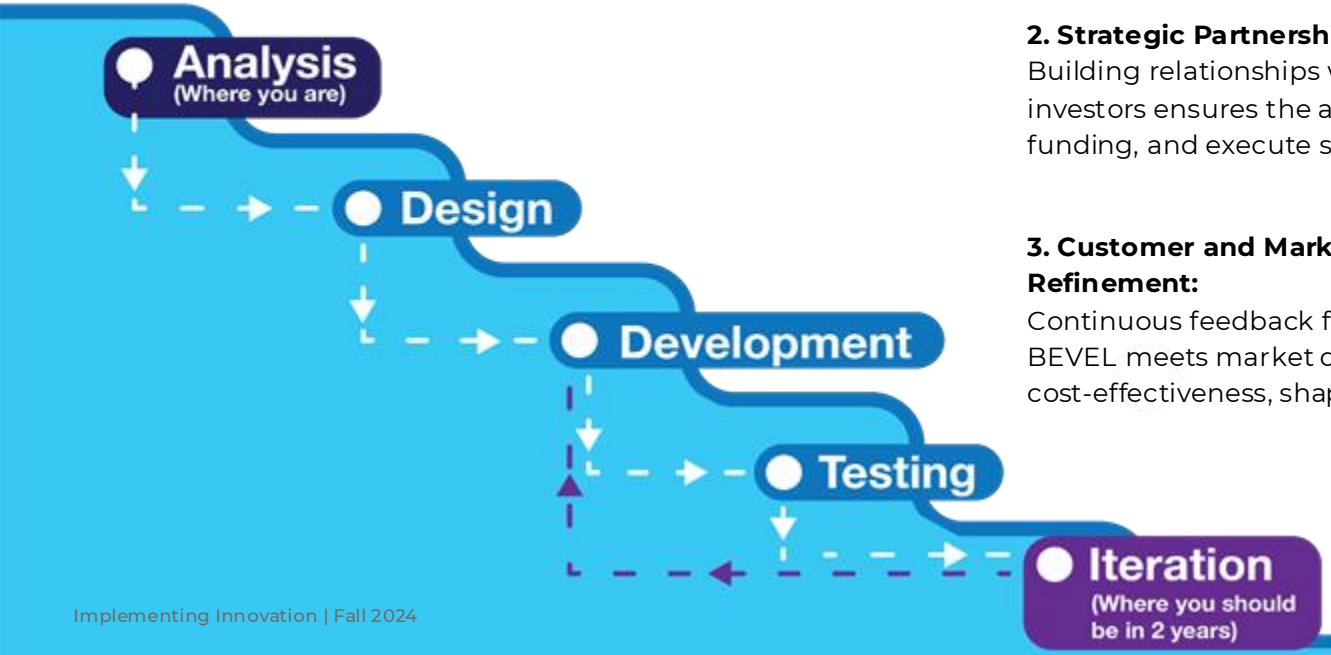
Other Competitors	VS	BAKS MEDICAL
Heavy & clunky	SIZE	Portable & Lightweight
Transfusion team	STAFF	One operator & One button
Expensive	COST	½ Cost of similar device
Care centers	SETTING	Care centers + Diverse critical settings
Sterile settings	TECH	Sterile + Non-sterile settings

Strategic Roadmap Overview



Wave 0

Where we are
VS
Where we need to be



1. Regulatory Approval and Product Development are the Core Foundations:
BEVEL must secure FDA compliance through DeNovo or 510k pathways while advancing from a prototype to a fully functional, market-ready device.

2. Strategic Partnerships and Funding Enable Scalability:
Building relationships with manufacturers, contractors, and investors ensures the ability to scale production, secure funding, and execute successful clinical trials.

3. Customer and Market Validation Drive Product Refinement:
Continuous feedback from healthcare providers ensures BEVEL meets market demands for portability, ease of use, and cost-effectiveness, shaping final design.

Wave 1

CUSTOMER & INFLUENCERS

High-trauma urban cases are common, yet often lack effective solutions to manage blood loss on-site before patients can be transported to the hospital for care.

Among patients who arrive at the emergency department with trauma, hemorrhage is the leading cause of death within the first hour. Within the first 24 hours of arrival to the emergency department, nearly 50% of deaths result from hemorrhage.

National Library of Medicine

Why start in urban healthcare settings?

Focus

Trauma related injuries are currently one of the leading causes of death in the United States.

Urban centers experience higher rates of violent crime, car accidents, and severe injuries that require immediate care

Urban trauma centers saw a higher proportion of patients with very severe injuries (Injury Severity Score >25)

2018 National Crime Victims' Rights Week Resource Guide: Crime and Victimization Fact Sheets

Despite their proximity to large hospitals, urban healthcare systems are often overwhelmed by demand.

Reviews for urban hospitals mention "sick people in the hallways" and "people sleeping in the halls," suggesting overcrowding issues.

The Coming Collapse of the U.S. Healthcare System, TIME Magazine

Once validated in urban settings, where trauma and blood loss incidents are frequent, the technology can be iterated and scaled to sterile and rural contexts

Assumption to test: Partnerships with urban trauma centers will facilitate the successful validation of the technology, and these early adopters will act as key opinion leaders (KOLs) and influencers, helping drive acceptance and adoption in other healthcare settings.

*sterile environments (ORs) in rural hospitals can be addressed only after we gain FDA sterilization certification

Assumption tested: Trauma 1 facilities prioritize patient stabilization and use processes like autotransfusion. This indicates a differentiation in roles across hospital types, affecting how and where autotransfusion protocols could be implemented.

Who will be our customers?

Where	**Trauma 1 and 2 Urban Hospitals**	**Emergency Medical Services & Transport**	**OBGYN Urban Hospitals* (L+D)**
Users	Trauma Surgeons, Emergency Department Staff,	Paramedics, Emergency Medical Technician (EMT), and physicians	Attending OB physicians, L+D nurses
High-level decision-maker & influencers	Trauma Program Managers & Trauma Program Director	Emergency medical Service systems (e.g. MIEMSS)	Hospital purchasing staff, leadership, and medical workers, government body overseeing healthcare

Patient

Urban residents, particularly:
Patients with traumatic injury experiencing acute blood loss (Thoracic trauma) during transport and before hospital arrival
Mothers experiencing PPH, ectopic bleeding in L+D rooms and during transport

*sterile environments (ORs) in rural hospitals can be addressed only after we gain FDA sterilization certification

Our value proposition in urban settings

Patients need to wait for transport in order to receive transportation

Bevel gives the ability for urban providers to do emergency transfusions before transporting a patient to a healthcare center.

A study by Vamvakas and Taswell estimated the demand for RBC transfusions to increase by 64% from 1989 till 2030 in the USA, with a potential shortfall of nearly 4 million RBC units by 2030 (Result 1
Experts Suggest Innovations to Address Global Blood Crisis, HMS

Current transfusion devices require training and high touch tech requirements

Bevel eliminates the need for trained technician during critical care needs.Bevel's easy to use design allows medical workers in EMT to spend more time with the patient instead of operating a device

"Getting into the prehospital is also a great way to get into the market. I have heard they are pushing for ambulances to have whole blood on them"
Critical Care Worker

No devices allow for transfusion in non-sterile settings

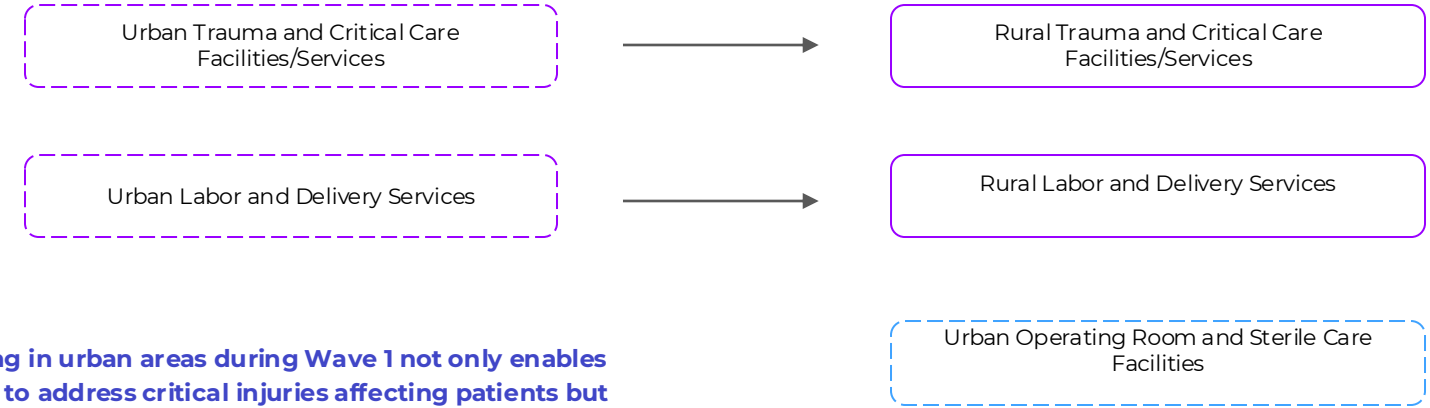
Bevel will provide rural and urban hospitals ability to do autotransfusion in the ORs. Bevel allows healthcare providers to perform auto transfusions in settings where blood shortages pose significant risks to patient safety.

"Not having whole blood when get a lot of trauma cases like gunshot wounds is hard because even if we are not a trauma center we need those resources "
Critical Care Worker

How do we enter the urban market and set the stage for future stages?

In this wave, BAKS Medical should focus on introducing Bevel to trauma care in urban settings, while simultaneously setting a pathway to enter rural healthcare settings in the future.

Wave 1



Testing in urban areas during Wave 1 not only enables BAKS to address critical injuries affecting patients but also positions us for future expansion into regions facing blood shortages. This experience will further prepare BAKS for piloting solutions in sterile OR environments.

Key activities for BAKS Medical to succeed in the urban market

Conduct Initial Clinical Trials for Efficacy and Effectiveness

Create trial protocols to evaluate the device's impact on patient outcomes in trauma and L&D settings.

Collaborate with urban hospitals to enhance recruitment and integrate the device into clinical workflows

Establish monitoring and reporting strategies to refine the device and support regulatory submissions.

Develop Regulatory Strategies and Finalize De Novo Approval

Engage with regulatory bodies, such as the FDA, to discuss the device's classification and confirm the pathway for De Novo approval

Develop specific protocols that address sterile practices, including infection control measures and data collection methods that comply with operating room standards

Expand Clinical Operations for Rural Market Integration

Identify and evaluate potential urban hospitals and trauma centers that align with the trial objectives and patient demographics.

Implement a robust training program for site staff to standardize procedures and ensure consistency in data collection and patient care across all trial locations.

Technology & data initiatives to succeed in the rural market

Continuous R&D for product iteration based on clinical trial feedback; evidence needed.

Conduct technical testing on aspects of BEVEL, like UV light process to ensure feasibility

Security and Safety: to comply with FDA HIPAA, and develop safety sterilizations protocols to pass FDA standardization (Sterilization Process controls Evidence).

Build data systems that collect, analyze, and report performance metrics for use in future trials and potential value offerings (i.e. creation of a robust data platform)

Assumption tested: There is a distinction between EMS and Paramedics, with Paramedics being more equipped to handle complex procedures. This suggests that any implementation of autotransfusion protocols in pre-hospital care would need to consider the training and expertise of the responders

Key people and partnerships to facilitate BAKS' entry and expansion in the urban market and beyond

Establish Collaborations with Rural Hospitals for Wave 2 Clinical Trial Sites

Develop formal agreements outlining roles, responsibilities, and expectations for trial execution, as well as securing KOL endorsements and participation to drive adoption and credibility.

Leverage Manufacturers for Scaling and Streamlining Complex Devices

Identify and engage medical device manufacturers with proven scalability, and negotiate co-development partnerships to leverage their expertise in optimizing design for manufacturability

Engage Maternal Care Hospitals with Connections to Rural Clinics

Initiate strategic discussions with maternal care hospitals and establish a collaborative framework with shared goals and resources to align efforts and maximize impact across rural networks

Gain Endorsements from Key Opinion Leaders

Develop an outreach strategy to engage Key Opinion Leaders in maternal and trauma care, organizing roundtables to gather insights and position them as device advocate

Wave 2

CUSTOMER & INFLUENCERS

Providing life-saving measures for blood loss is a big problem for low-resourced settings, and not just in postpartum care.

50%

motor vehicle crash-related fatalities occur in rural areas

47 **Million**

People Live **1+ hour** away from the Trauma Centre

Longitudinal experience with the RTTDC: Improving outcomes through collaboration

Sudden Impact vs Distance and Time: Rural Patients and Trauma Care

Who will be our customers?

Assumption to test: There is a way to use autotransfusion for most cases critical conditions of blood loss in rural areas (i.e. there is an appropriate cavity to collect blood)

Talk to more physicians when prototype is ready.

Where?	**Critical Access Centers and Rural Hospitals (Non-sterile & sterile environments)**	**Emergency Medical Services & Transport (e.g. ambulances, MedEvac. etc.)**	**Trauma 1 or 2 Hospitals**
Users	*Attending physicians, critical care nurses*	*Paramedics, Emergency Medical Technician (EMT), and physicians*	*Trauma Surgeons, Emergency Department Staff,*
High-level decision-maker & influencers	*Hospital purchasing staff, leadership, and medical workers, government body overseeing healthcare*	*Emergency medical service systems (e.g. MIEMSS)*	*Trauma Program Managers & Trauma Program Director*

Patient

Rural residents, particularly:
- Mothers experiencing PPH, ectopic bleeding in *labor & delivery rooms*
- Patient with traumatic injury experiencing acute blood loss (Thoracic trauma) in *ERs and in the field*
- Patients in surgeries experiencing blood loss (e.g. orthopedic surgery, cardiac surgeon) in *ORs*

*sterile environments (ORs) in rural hospitals can be addressed only after we gain FDA sterilization certification

Why go rural now?

We can achieve impact and volume in rural areas, as they struggle with unaddressed needs and lack of options.

Assumption to test: Rural hospitals will be willing and able to afford a device like Bevel, in a way that is still profitable for BAKS Medical.

Obtain a clearer picture of manufacturing costs of Bevel, and interview purchasing departments to understand rural willingness/ability to pay.

Patients in rural areas are twice as likely to die of traumatic injuries than their more urban counterpart.

Limited access to critical care and resources.

30%

Higher mortality rate when treated in non-trauma centers

2x

Increased mortality due to traumatic injuries in rural areas

Patients need to travel far to get the care they need.

5 Mile Increase

Distance from trauma center increased the likelihood of mortality by **8 %**

Lack of blood supply and autotransfusion capabilities.

"I have run out of blood the night of the ectopic pregnancy we used all the blood in the blood bank"- Lexie (critical access doctor)

"We're just not sure how we would reach the rural and remote locations cost-effectively..."

(Jon, COO of Midwest Blood)

Longitudinal experience with the RTTDC: Improving outcomes through collaboration.

Our value proposition in rural settings with Bevel

Limited access to critical care and resources.

Bevel can be a temporary stabilization measure before reaching the more resourced areas

Bevel provides clean blood in non-sterile environment via UV light.

"You know, and when I say critical access, the entire staffing of the department would be me and two nurses."

Patients need to travel far to get the care they need.

Bevel is designed to be a portable solution which can increase access to patient blood during pre-hospital events

Bevel's easy to use design allows medical workers in EMT to spend more time with the patient instead of operating a device.

"I'm on the phone and trying to get them shipped out as quickly as possible."

Lack of blood supply and autotransfusion capabilities.

Bevel gives the ability for rural providers to do emergency transfusions even without blood supply.

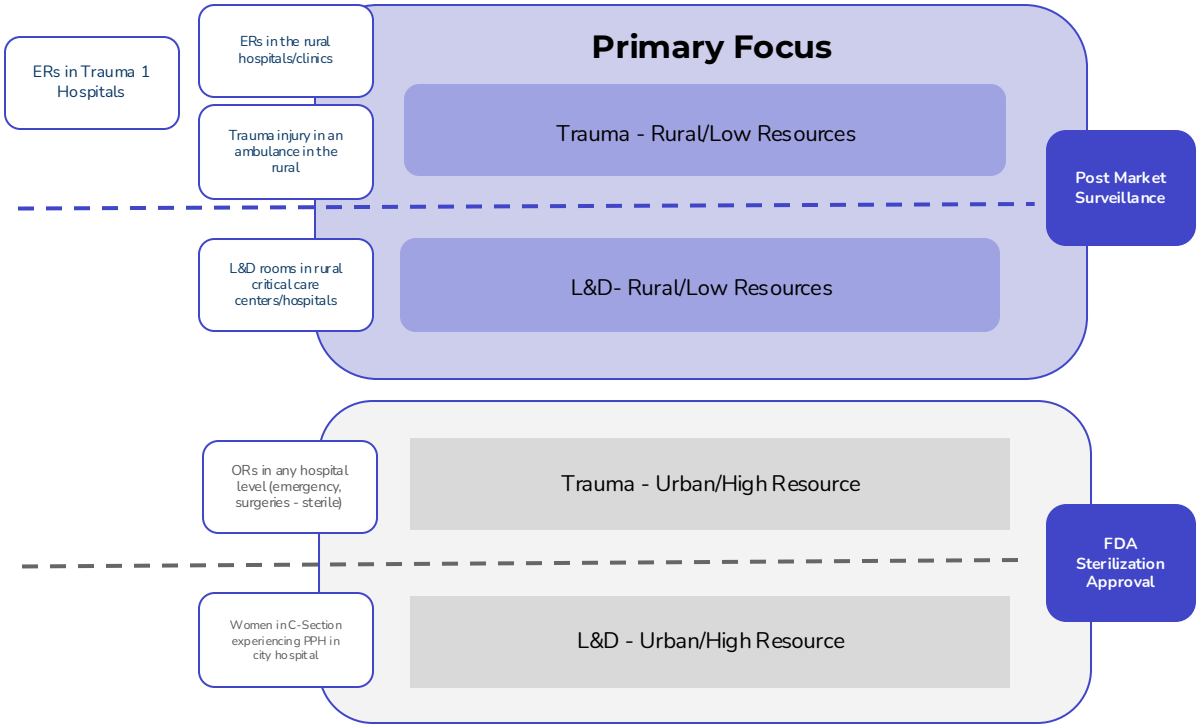
Bevel eliminates the need for trained technician during critical care needs.

Bevel provides rural hospitals ability to do autotransfusion in the ORs.

"I'll order some on [website] and call the blood bank... Even that can be a challenge. Just getting the blood from the blood bank at a place like that can take an hour or two or more."

How do we enter the rural market?

In this wave, BAKS Medical should focus on introducing Bevel to L&D rooms and trauma care in rural settings, while simultaneously setting a pathway to enter the sterile ORs in the future.



Assumption to test: Urban hospitals will be willing to partner with us to obtain the FDA Sterilization Certification–there is enough need for Bevel in urban ORs.

Interview physicians and decision-makers in urban hospitals to gauge interest of having Bevel in ORs.

Key activities for BAKS Medical to succeed in the rural market

BAKS Medical should focus on building cost-effective distribution channels, forge relationships and build knowledge of rural environments, and obtain necessary certifications & validations.

Build logistics, distribution, and communication channels

Develop a **distribution network** in a cost-effective way

Develop **training programs** or **certification**s to educate rural medical workers to utilize Bevel

Build partnerships with rural stakeholders

Prove the use case and viability of Bevel in rural environments.

Consider **reimbursement strategies** - which rural insurance coverage would cover Bevel?

Obtain real-world evidence (RWE) - **data collection in post-market surveillance,** usability and implementation studies

Test pricing strategies for rural settings

Obtain FDA Sterilization certification so Bevel can be utilized in ORs.

Start **FDA sterilization certification** process for Bevel in urban settings

Begin **introducing** Bevel into **sterile environments (ORs)**, doing trials if necessary

Assumption to test: Bevel can be integrated seamlessly into the rural healthcare ecosystem, with buy-in from stakeholders.

Understand the rural ecosystem more via expert interviews and visits.

People, Partnerships and Organizations

Integrating with existing health innovation ecosystem

ARPA-H (Advanced Research Projects Agency for Health) for funding and scaling the product across rural regions

Developing partnership with **training programs and regional experts** for staff training.

Partnering with rural health and state health organizations

Work with organizations like the **National Rural Health Association** or state Offices of Rural Health

Working with **Emergency Medical Service Systems** (For example MIEMSS)

Developing research partnerships for product validation

Partner with **universities or research centers** focused on rural health to **validate** the device's effectiveness in rural settings

Wave 3 CUSTOMER & INFLUENCERS

Providing rapid and efficient trauma care in disaster and combat areas is crucial, especially when conventional blood supplies are inaccessible

90%

of combat-related deaths occur before reaching a medical treatment facility, highlighting the need for immediate medical intervention in combat zone.

Source

BAKS Medical

Who will our customers be?

Where	Trauma Combat Zones	Disaster Relief Areas
Users	Combat medics, field surgeons, and soldiers with basic medical training.	EMS in Disaster Relief Operations: Search and rescue teams.
High-level decision-maker & influencers	Military leadership and logistics coordinators.	Emergency management agencies overseeing disaster response.

Patient

Individuals in combat zones experiencing traumatic injuries.
Victims of disasters requiring **immediate trauma care where conventional blood supplies are inaccessible.**

Our value proposition for high-stress settings with Bevel

Patients need *immediate stabilization* and care

"In disaster areas where rapid and efficient trauma care is essential, having autotransfusion devices available can significantly enhance survival rates."

Bevel allows **temporary stabilization** of patients before they can be evacuated to more resourced areas.

Provides a crucial solution for managing blood loss in high-stress, resource-constrained environments.

Limited access to critical care and resources

"Using the patients blood reduces the risk of any diseases because you are getting your own blood back"

Bevel is capable of functioning where sterile environments are unavailable or compromised.

It **reduces the risks of blood-borne diseases a**nd improves patient outcomes in non-sterile, high-stress environments.

Lack of *blood supply and appropriate conditions* for transfusion

Bevel enables blood transfusion independence, essential in areas with no immediate access to blood banks.

Bevel can rapidly collect and process blood for autotransfusion, offering a vital option in combat zones where traditional transfusions are not feasible.

Provides timely help and operational simplicity, making it viable for use in combat relief.

Scaling Operations for Disaster and Combat Zones

Introducing Bevel to the non-sterile non-healthcare area through the following initiatives

Set up scalable operational processes for R&D

to streamline operations to support expansion.

Offer customizable configurations of BEVEL

to meet the specific needs of different deployment spaces.

Define Regulatory Strategies for dual FDA and DoD pathways

to define regulatory processes for clinical trials in non-sterile healthcare and field clinics.

People & partnerships to facilitate entry into combat, and disaster relief

Integrating with Military and Disaster Relief Ecosystems

Collaborate with organizations like the **Defense Health Agency (DHA), DARPA**, and the **Combat Casualty Care Research Program (CCCRP)** to innovate and optimize the device for high-stress conditions.

Utilize success in urban settings as leverage to gain **trust and credibility** in combat zones and disaster relief operations.

Partnering with Military and Disaster Relief Organizations

Work with disaster relief organizations like **MedShare** to coordinate rapid deployment of medical supplies in emergencies.

DoD Pathway - Partner with above military medical researchers to test the device in **field/medevac situations.**

Developing Research Partnerships for Product Validation

Partner with military research centers to validate the device's effectiveness in combat settings through real-world experimentation.

Collaborate with the **National Disaster Medical System (NDMS)** to understand requirements interoperability and medical surge capacity during disasters.

Next Steps

BEVEL Autotransfusion Device: Commit to advancing the BEVEL device, pioneering auto-transfusion capabilities that recover and restore patient blood effectively in critical settings.

Regulatory Approval: Prioritize FDA compliance through the DeNovo pathway, transitioning from a prototype to a fully testable version.

Strategic Partnerships: Engage with investors, healthcare providers, and key opinion leaders to gather data, refine the product, and secure funding for large-scale production.

Market Entry: Conduct clinical trials in high-impact urban healthcare settings and gradually expand to rural environments, military trauma zones, and disaster relief areas.

THANK YOU