SurgiBox

*Safe Surgery any time, any place®*

Presenting
the award-winning
SurgiField™ System

ISO 13485 Quality Management System

EU-MDR CE

pmda

*SurgiBox Inc. is a Delaware registered C-Corp*

NATO and the U.S. military intend to push lifesaving surgical capability far forward into austere and contested environments.

# Future conflicts will stretch evacuation timelines. NATO and the U.S. Military recognize that the golden hour cannot be guaranteed. What can be done ?

- Push surgical capability forward: Both NATO and U.S. doctrine emphasize moving damage-control surgery to Role-2/FST-level echelons in austere environments when evacuation is delayed or contested (LSCO / A2AD contexts).

- Prolonged Field Care (PFC): JTS Clinical Practice Guidelines mandate forward interventions to sustain casualties beyond the "golden hour" when MEDEVAC is unavailable.

- Mobile surgical/resuscitative teams: Recent NATO/US papers highlight the need for small, transportable Role-2 augmentations capable of parallel surgeries in distributed operations.

# The SurgiField™: A rapidly deployed, cost-effective and ultra-portable surgical environment designed with US Army and Air Force surgeons:

Torso

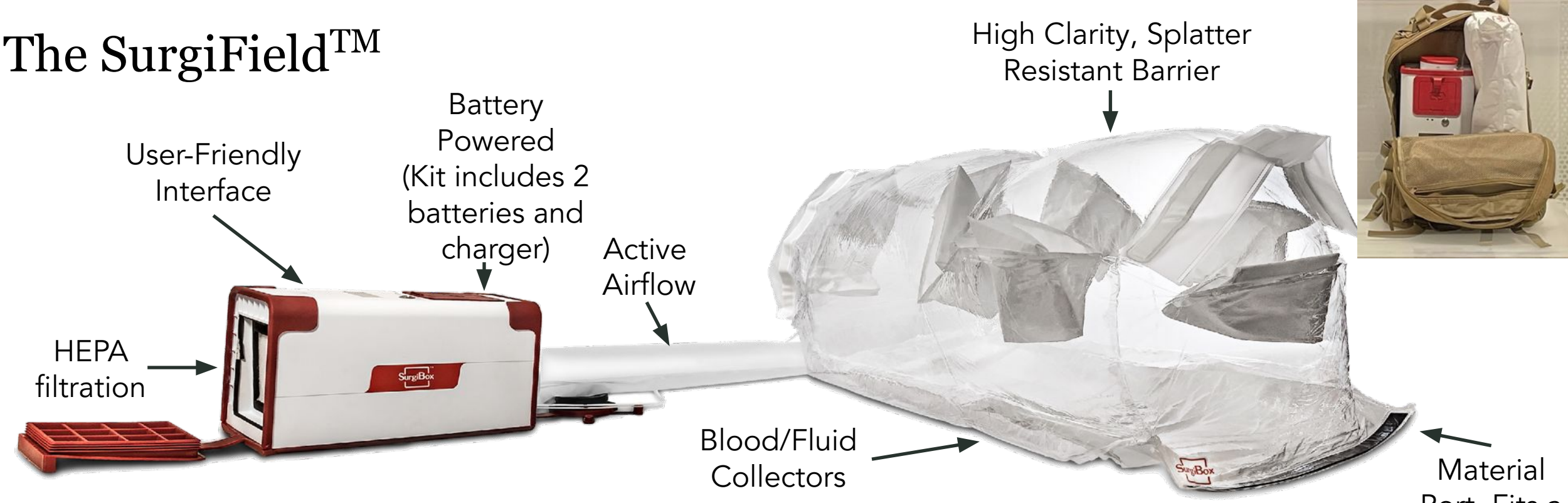
Limb

- protects the patient's surgical site from the outside environment and medical personnel;

- the medical provider from the patient's bodily fluids;

➔ Role-2 augmentation in a backpack
➔ Rapid setup for parallel surgeries
➔ Enables PFC & en-route resuscitation
➔ Low logistics footprint, NATO interoperable
➔ Force multiplier for SOF, MEU, Littoral ops

# The SurgiField™






Weight
< 6 kgs

Inflates
~ 120s

Each charge
4+ hours

Dual Patient-Provider Protection

"When you're operating with artillery fire in the distance and debris falling around you, you learn that medicine isn't about perfect conditions - it's about creating a moment of safety in chaos. The SurgiField gave us something I never thought possible in that building: better sterile conditions. For those 30 minutes, with my hands working inside that protective barrier, I could focus entirely on saving this young man's life instead of worrying about contamination. The system was intuitive even under pressure - clear visibility, easy access, and most importantly, it created a clean surgical field where none should have existed.

In conflict medicine, we're always improvising, but this felt like having a real operating room materialize around my patient. That's the difference between losing someone to infection days later and giving them a fighting chance to heal."
*Burmese Army Surgeon,*

Shrapnel removal in Burma

Real Life Impact In Ukraine through Emergency Use Authorization: “This equipment helps to save, firstly, time for processing the operating field, and secondly, it helps to ensure sterility in aggressive environments. Namely, in basements, tents, under the conditions of transportation by sanitary transport. This is what provides immediate operative access to a serious injury, ensures the preservation of the life of such an injured person where it is not possible to provide qualified assistance in the operating room.” (translated from original Ukranian),

*Lieutenant General, Ukraine*

Check out the full video here !

До військового шпиталю, що виконує завдання у Північній операційній зоні, передали портативні інноваційні системи «SurgiBox» для невідкладних хірургічних операцій в польових умовах. Про це повідомив командувач Об’єднаних Сил ЗС України генерал-лейтенант Сергій Наєв.

"If you're going to go to a surgically underserved country, you're going to try to find a hospital somewhere and that hospital may or may not have the infrastructure to support clean surgery. But when you think about the SurgiField, suddenly you don't need any of that. You can go to the patient instead of the patient coming to you."


*Prof.David King, Trauma Surgeon, Associate Professor, Massachusetts General Hospital and US Army Surgeon*


Japanese Surgeon and Military Simulating the SurgiField

# War Settings

The SurgiField was designed with trauma surgeons from US Army and US Air Force

## Field Surgery

- Field Hospitals / Naval Ships: Parallel surgeries, higher throughput.
- Prolonged Field Care: On-site surgery when evacuation impossible.
- Littoral Combat Ships: Makeshift operating rooms, major upgrade for surgeons.

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## Evacuation

- CASEVAC: Manage complications in flight, protect patients/crew.
- Medevac: Stabilization + transport,  wound protection

# Emergency, Austere and Remote Setting Scenarios

Emergency Settings (e.g. conflict and disaster zones) to enable the transformation of any space into a safe surgical environment with multiple "pop-up" operating theaters including:

- Existing infrastructure such as medical facilities - even those that have been damaged
- Infrastructure that can be set up on the go such as in tents, abandoned buildings and sheds

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Austere and Remote Settings (e.g. refugee camps, rural areas, mines, cruise ships) to enable the deployment of surgical missions in:

- Terrain (e.g. mountains and mines) where transporting patients is difficult
- Remote areas where no or poor operating theater infrastructure exists and/or reliance on distant referral hospitals is impractical

# The SurgiField™ has been developed with scientific rigor with results published in peer-reviewed journals

MILITARY MEDICINE, 186, S1:295, 2021

**A Paradigm Shift in Critical Care Infrastructure in Complex Settings: Evaluating an Ultraportable Operating Room to Improve Field Surgical Safety**

Debbie L. Teodorescu, MD; Stephen Okajima, MS; CPT Asad Moten, MC, USA; Mike H.M. Teodorescu, DBA; Majed El Hechi, MD; Samantha Gutierrez-Arango, BSc; Karien Meier, MD, MSc; Capt Robert J. Smalley, MC, USAF; COL David R. King, MC, USA

ABSTRACT

**Introduction:**
Scarcity of operating rooms and personal protective equipment in far-forward field settings make surgical infections a potential concern for combat mortality and morbidity. Surgical and transport personnel also face infectious risks from bodily fluid exposures. Our study aimed to describe the serial, proof-of-concept testing of the SurgiBox technology: an inflatable sterile environment that addresses the aforementioned problems, fits on gurneys and backpacks, and drapes over incisions.

**Materials and Methods:**
The SurgiBox environmental control unit and inflatable enclosure were optimized over five generations based on iterative feedback from stakeholders experienced in surgery in austere settings. The airflow system was developed by analytic modeling, verified through in silico modeling in SOLIDWORKS, and confirmed with prototype smoke-trail checking. Particulate counts evaluated the enclosure's ability to control and mitigate users' exposures to potentially infectious contaminants from the surgical field in various settings. SurgiBox enclosures were setup over a mannequin's torso, in a configuration and position for either thoracic or abdominal surgery. A particle counter was serially positioned in sternotomy and laparotomy positions, as well as bilateral flank positions. This setup was repeated with open ports exposing the enclosure to the external environment. To simulate stress scenarios, sampling was repeated with enclosure measurements during an increase in external particulate concentration.

**Results:**
The airflow technology effectively kept contaminants away from the incision and maintained a pressure differential to reduce particle entry. Benchtop testing demonstrated that even when ports were opened or the external environment had high contaminant burden, the enclosed surgical field consistently registered 0 particle count in all positions. Time from kit opening to incision averaged 54.5 seconds, with the rate-limiting step being connecting the environmental control unit to the enclosure. The portable kit weighted 5.9 lbs.

**Conclusions:**
Analytic, in silico, and mechanical airflow modeling and benchtop testing have helped to quantify the SurgiBox system's reliability in creating and maintaining an operating room-quality surgical field within the enclosure as well as protecting the surgical team outside the enclosure. More recent and ongoing work has focused on specifying optimal use settings in the causality chain of care, expanding support for circumferential procedures, automating airflow control, and accelerating system setup. SurgiBox's ultimate goal is to take timely, safe surgery to patients in even the most austere of settings.


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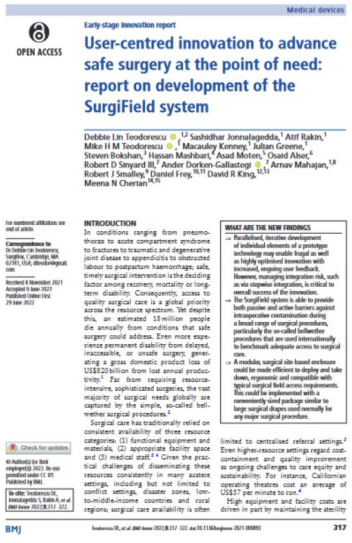
- Military Medicine (Link Here)
- Results of the benchtop testing



Medical devices

OPEN ACCESS

Early-stage innovation report

**User-centred innovation to advance safe surgery at the point of need: report on development of the SurgiField system**


Debbie Lin Teodorescu, Sashidhar Jonnalagedda, Atif Rakin, Mike H M Teodorescu, Macauley Konney, Julian Greene, Steven Bokshan, Hassan Mashbari, Asad Moten, Osaid Alser, Robert D Sinyard III, Ander Dorken-Gallastegi, Arnav Mahajan, Robert J Smalley, Daniel Frey, David R King, Meena N Cherian


INTRODUCTION

In conditions ranging from pneumothorax to acute compartment syndrome to fractures to traumatic and degenerative joint disease to appendicitis to obstructed labour to postpartum haemorrhage, safe, timely surgical intervention is the deciding factor among recovery, mortality or long-term disability. Consequently, access to quality surgical care is a global priority across the resource spectrum. Yet despite this, an estimated 1.8 million people die annually from conditions that safe surgery could address. Even more experience permanent disability from delayed, inaccessible, or unsafe surgery, generating a gross domestic product loss of US$520 billion from lost annual productivity.[1] Far from requiring resource-intensive, sophisticated surgeries, the vast majority of surgical needs globally are captured by the simple, so-called bellwether surgical procedures.[2]

Surgical care has traditionally relied on consistent availability of three resource categories: (1) functional equipment and materials, (2) appropriate facility space and (3) medical staff.[3 4] Given the practical challenges of disseminating these resources consistently in many austere settings, including but not limited to conflict settings, disaster zones, low-to-middle-income countries and rural regions; surgical care availability is often limited to centralised referral settings.[2] Even higher-resource settings regard cost-containment and quality improvement as ongoing challenges to care equity and sustainability. For instance, Californian operating theatres cost an average of US$37 per minute to run.[4]

High equipment and facility costs are driven in part by maintaining the sterility

WHAT ARE THE NEW FINDINGS

- Paradigmatic, iterative development of individual elements of a prototype technology may enable frugal as well as highly optimised innovation with increased, ongoing user feedback. However, managing integration risk, such as via stepwise integration, is critical to overall success of the innovation.
- The SurgiField system is able to provide both passive and active barriers against intraoperative contamination during a broad range of surgical procedures, particularly the so-called bellwether procedures that are used internationally to benchmark adequate access to surgical care.
- A modular, surgical site-based enclosure could be made efficient to deploy and take down, ergonomic and compatible with typical surgical field access requirements. This could be implemented with a conveniently sized package similar to large surgical drapes used normally for any major surgical procedure.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- BMJ Innovations (Link Here)
- Results of the co-development process with surgeons and medical personnel

European Journal of Trauma and Emergency Surgery
https://doi.org/10.1007/s00068-023-02410-w

ORIGINAL ARTICLE

**Moving toward point-of-care surgery in Ukraine: testing an ultra-portable operating room in an active war zone**


Emanuele Lagazzi · Debbie Lin Teodorescu · Dias Argandykov · Michael Alexander Samotowka · David Richard King



Received: 26 September 2023 / Accepted: 19 November 2023




**Abstract**

**Purpose** In conflict zones, providers may have to decide between delaying time-sensitive surgeries or performing operative interventions in the field, potentially subjecting patients to significant infection risks. We conducted a single-arm crossover study to assess the feasibility of using an ultraportable operating room (U-OR) for surgical procedures on a porcine cadaver abdominal traumatic injury model in an active war zone.

**Methods** We enrolled participants from an ASSET-type course designed to train Ukrainian surgeons before deployment to active conflict zones. They performed three standardized consecutive abdominal surgical procedures (liver, kidney, and small bowel injury repair) with and without the U-OR. Primary outcomes included surgical procedure completion rate, procedure time, and airborne particle count at the start of surgery. Secondary survey-based outcomes assessed surgery task load index (SURG-TLX) and perceived operative factors.

**Results** Fourteen surgeons performed 76 surgical procedures (38 with the U-OR, 38 without the U-OR). The completion rate for each surgical procedure was 100% in both groups. While the procedure time for the liver injury repair did not differ significantly between the two groups, the use of the U-OR was associated with a longer time for kidney (155 vs. 56 s, $p = 0.002$), and small bowel (220 vs. 103 s, $p = 0.004$) injury repair. The average airborne particle count within the U-OR was substantially lower compared to outside the U-OR (6,753,852 vs. 232,282 n/m$^3$, $p < 0.001$). There was no statistically significant difference in SURG-TLX for procedures performed with and without the U-OR.

**Conclusion** The use of the U-OR did not affect the procedure completion rate or SURG-TLX. However, there was a marked difference in airborne particle counts between inside and outside the U-OR during surgery. These preliminary findings indicate the potential feasibility of using a U-OR to perform abdominal damage-control surgical procedures in austere settings.



**Keywords** Trauma · Emergency general surgery · Austere environment · Disaster medicine · Ukraine



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Springer

- Pubmed (Link Here)
  Results of a study in Lviv Ukraine

# Shipping Information

| | SKU | Package Weight (cms) | Package Dimensions | Shelf Life/Warranty |
|---|---|---|---|---|
|  | SB-T1-02-CE Carton of CE SurgiBubbles (6x) | 62.35 x 51.4x35.3 | 8kgs | 2 Years |
|  | EB-T1-02-EU:<br>1 Smart control Module<br>1 Smart Charger EU<br>2 Lithium Batteries<br>2 Pop-Up Frames | Box 1: 45.0 x 32.2 x 28.6<br>Box 2: 97 x 10 x 10 | Box 1: 6.75 kgs<br>Box 2: 0.3 kgs | 2 Years |


[TIME Magazine's Best Inventions of 2023]

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