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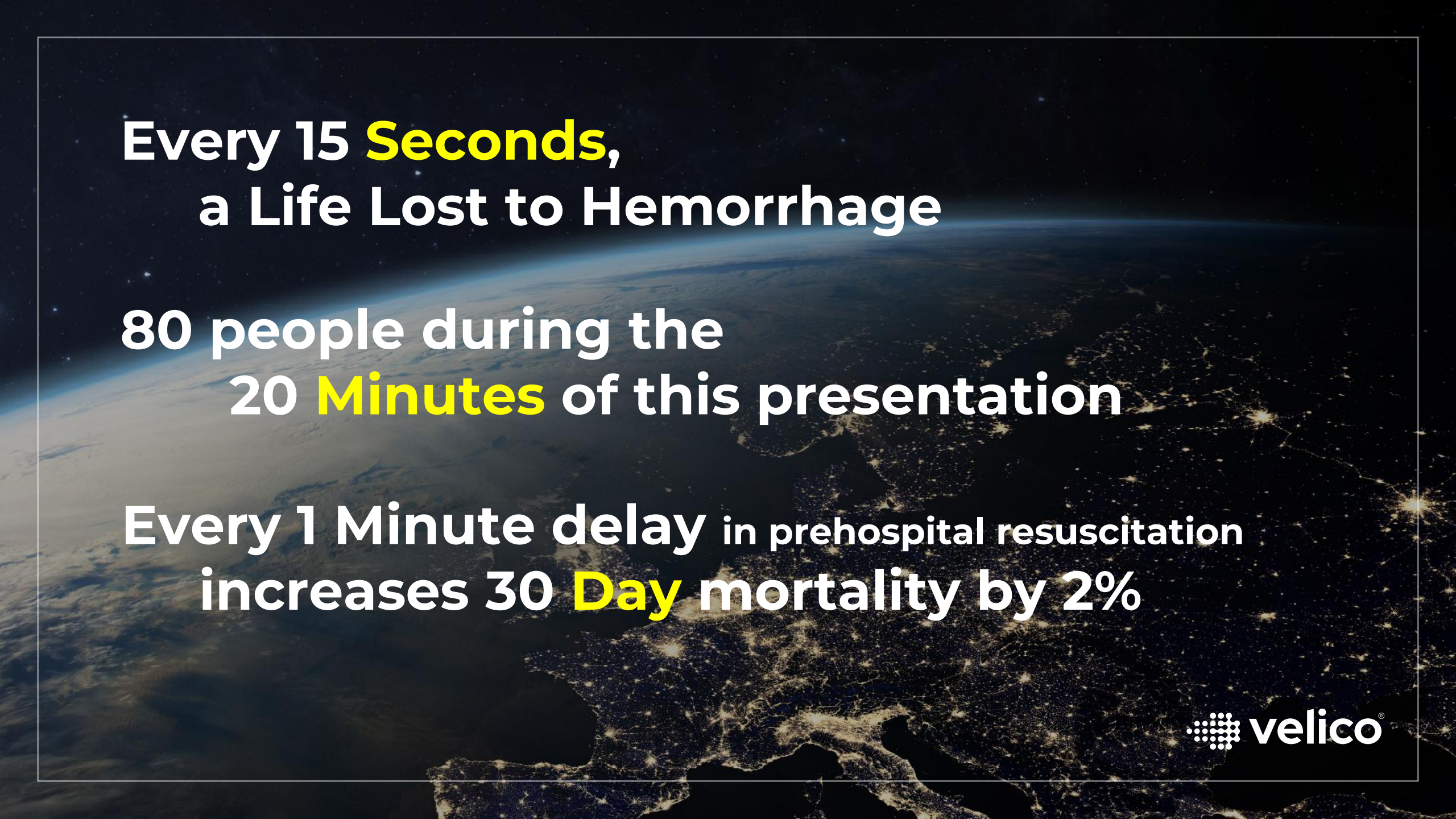
The Future of Blood

Dry Plasma: From Battlefield Past To Battlefield Future

Presenter

Ciaran Flanagan
Chief Marketing Officer, Velico

Spray Drying System not available for sale. FrontlineODP™ System not yet submitted to FDA for review. Programme funded by Barda. Contract number #75a50121c00059


Every 15 Seconds,
a Life Lost to Hemorrhage
80 people during the
20 Minutes of this presentation
Every 1 Minute delay in prehospital resuscitation
increases 30 Day mortality by 2%
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Plasma Works. Access Doesn't.

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 JULY 26, 2018 VOL. 379 NO. 4

Prehospital Plasma during Air Medical Transport in Trauma Patients at Risk for Hemorrhagic Shock

J.L. Sperry, F.X. Guyette, J.B. Brown, M.H. Yazer, D.J. Triulzi, B.J. Early-Young, P.W. Adams, B.J. Daley, R.S. Miller, B.G. Harbrecht, J.A. Claridge, H.A. Phelan, W.R. Witham, A.T. Putnam, T.M. Duane, L.H. Alarcon, C.W. Callaway, B.S. Zuckerbraun, M.D. Neal, M.R. Rosengart, R.M. Forsythe, T.R. Billiar, D.M. Yealy, A.B. Peitzman, and M.S. Zenati, for the PAMPer Study Group*

10% Reduction in Mortality if Plasma Administered Pre-Hospital

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Prerequisite Assumptions

1. **Pre-hospital blood / plasma** (GOOD) 
2. **Current availability** (NOT GREAT) 
3. **Solving accessibility & distribution** (GOOD) 
4. **Sovereign independence** (AMAZING) 

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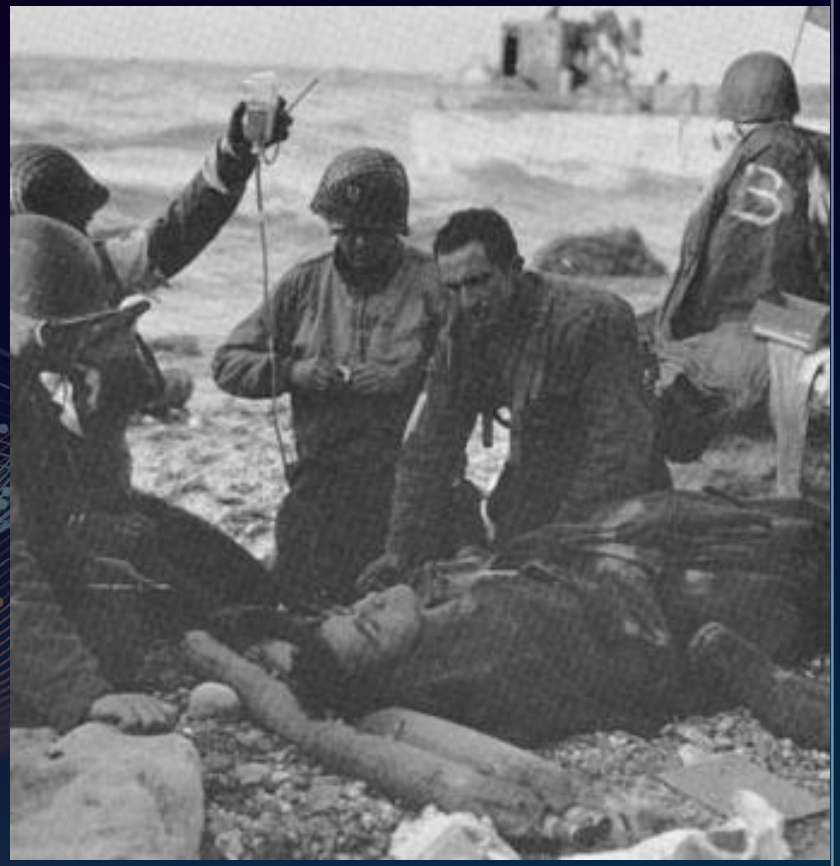
War: The Mother of Medical Invention

10 Million Units



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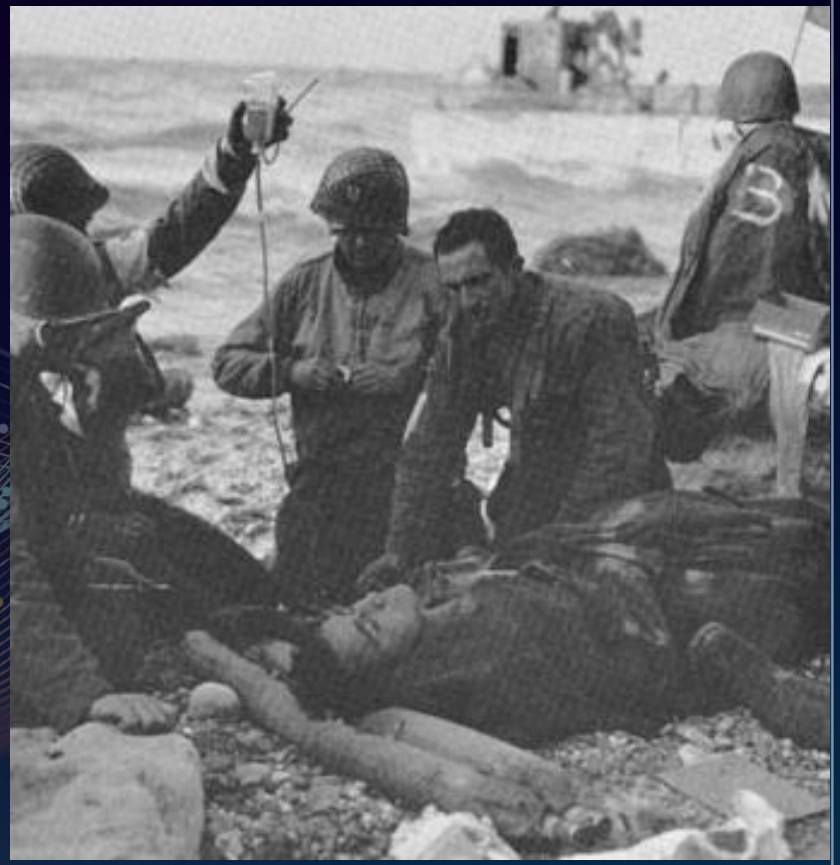
War: The Mother of Medical Invention

- Portable
- Easy to prepare
- Rugged
- Shelf-stable
- Sterile



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1950’s-2000’s: 50 Years of Decline

- Hepatitis from dry plasma transfusions identified by end of WWII; believed benefits outweighed the risks
- Attempts at pathogen reduction including reduction of pool sizes failed
- Discontinued due to risk of HBV contamination from large donor pools
- 1950’s Dry plasma use discontinued by US and Britain
- Serum albumin replaces dry plasma as primary resuscitation fluid for US soldiers

Dried Plasma

WORKS

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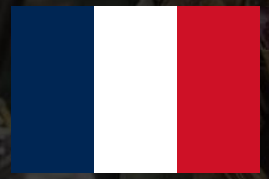
From Forgotten Technology to Urgent Priority












"Dried plasma is an urgent priority for trauma readiness."

Journal of Trauma (2023)

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Demand Outpaces Supply

Global Demand: **Dried Plasma** (Military)

NATO
OTAN

100,000 – 500,000 units

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Global Demand: Dried Plasma (Civilian Pre-Hospital)

NATO
OTAN

250,000 units

Population
958 Million

No. Civilian Ambulances
125,000

x2

2 Units Dried Plasma
per Ambulance
250,000

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How many units of Dried Plasma can we make now?

30,000

(units/p.a.)

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Far Forward, Ready to Use

Ready. Rugged. Rapid.

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Current state of dried plasma availability

- French Military FDP (FLYP or PLYO)
  - Available to French Military; limited civilian use
  - Available to U.S. SOCOM only first under EA-IND, now EUA*; very limited
  - France: collected from military donors
  - U.S. military collects FFP, ships to France for lyophilization
  - Glass bottles, minipool of A+B+AB considered universally compatible
  - In vitro data, historical use data, limited RCT data, no formal Phase 1, 2, 3

- German Red Cross (LyoPlas N-w)
  - Available to Germany for civilian & military use
  - Limited use outside Germany (UK, CAN, DEN, NOR, Israel, others)
  - Glass bottles, single donors
  - In vitro data, historical use data, limited RCT data, no formal Phase 1, 2, 3

*Note: EUA is for U.S. military use in combat, when plasma is not available or its use is inconvenient.

Current state of dried plasma availability

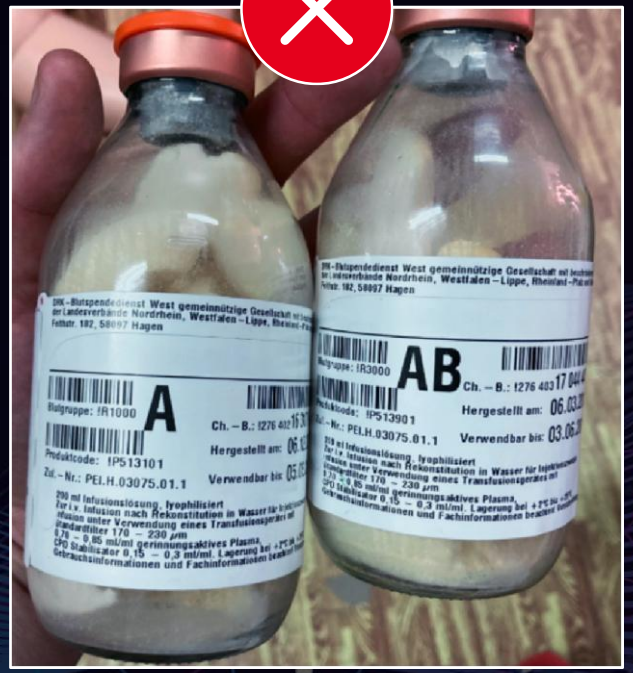
- Octapharma Octaplas LG lyo (pooled S/D pathogen reduced)
  - Recently CE-marked
  - Available to U.S. military only under EUA*
  - Glass bottles, supplied as A or AB
  - In vitro data, historical use of liquid Octaplas LG, no formal Phase 1, 2, 3

- South African Bioplasma FDP (pooled S/D pathogen reduced)
  - Available in South Africa for civilian & military use
  - Glass bottles [essentially Octaplas manufactured under license]
  - In vitro data, historical use, no formal Phase 1, 2, 3

*Note: EUA is for U.S. military use in combat, when plasma is not available or its use is inconvenient.

Glass Bottles:

Heavy, Cumbersome & Breakable



Ready. Rugged. Rapid.

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U.S. dried plasma under development

- Teleflex EZPlaz
  - DoD funded, centralized manufacturing, fixed capacity, US sourced plasma only
  - Single donor, plastic container, **lyophilized**, type-specific
  - In vitro data, completed Phase 1, no safety concerns, further clinical development planned

- Velico Medical Frontline ODP
  - HHS/BARDA funded, distributed manufacturing at blood centers around the world, modular & scalable manufacturing
  - Mobile, containerized, turn-key manufacturing systems
  - Single donor or pooled, plastic container, **spray-dried**, compatible with pathogen reduction technologies
  - In vitro data, completed Phase 1, no safety concerns per FDA, further development planned
  - Systems delivered/operational: US (multiple locations including US military), UK (MOD/NHSBT collaboration), Netherlands, Australia (others pending)

35 Minute Production

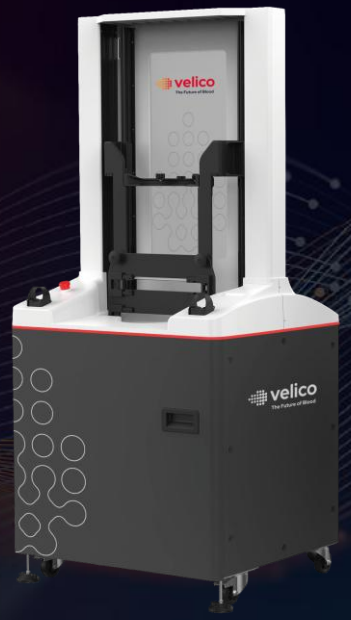
Spray Dried Plasma

FrontlineODP™ Spray Dried Plasma Manufacturing System

FrontlineODP™ (On Demand Plasma)

Plasma

VeliDryer



VeliSealer

Transfusion ready in 2.5 minutes

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Donate & Dry

- Drying machines at donor locations
- Enable **resilience & hyper-scalability**
- Remove cold chain, cost and waste

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Donate & Dry: under one roof

NHS BT - Cambridge

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User Friendly

Lightweight Packaging
Dried Plasma, SWFI & Transfer Line

Reconstitutes
with 200ml SWFI
(Sterile Water for Infusion)

within **2.5 minutes**

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Shelf Stable & Long Lasting

Targets:

- **2 Years**
  Refrigerated
- **1 Year**
  Room Temperature

Traceable – Scalable – Cost Effective

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Cost Effective

- At least **40% cheaper** than competition
- Long term sustainable infrastructure
- Just in time scalability

#PlasmaEverywhere

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Field Deployable Dried Plasma Production

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One container

18,000

Units of Dry Plasma per Year

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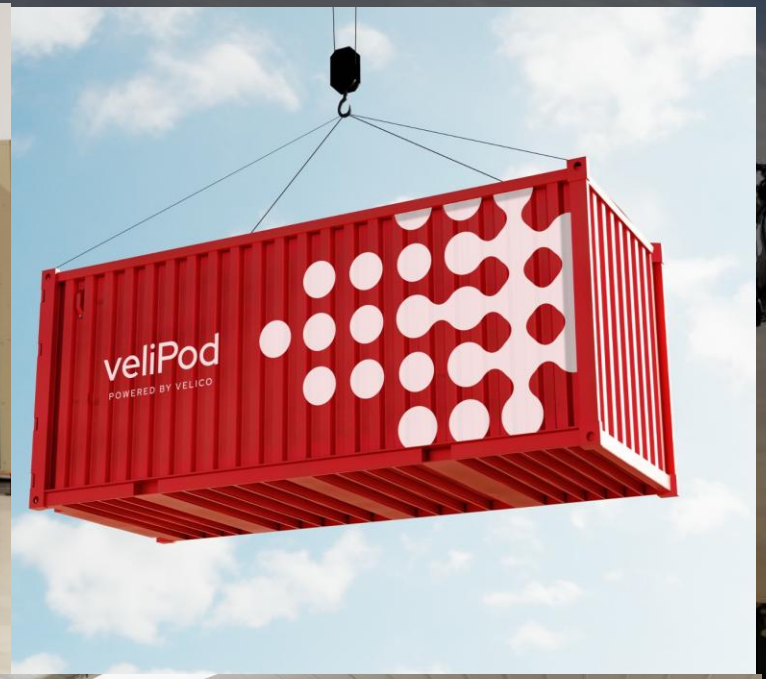
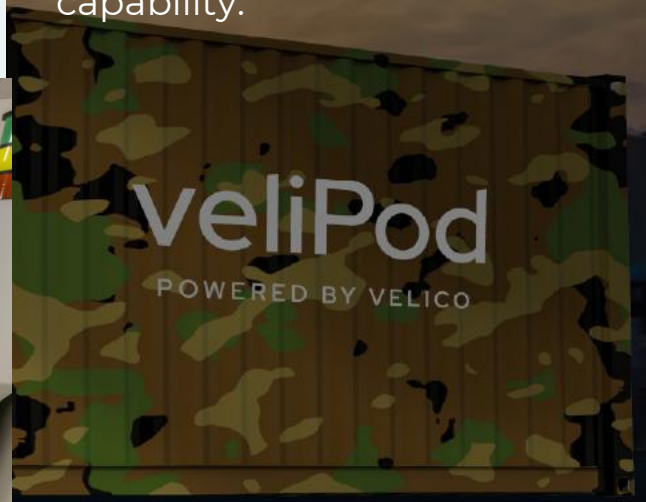


VeliPod: The solution to the medical/military campus real estate challenge
while adding a potential global rapid deployment capability.



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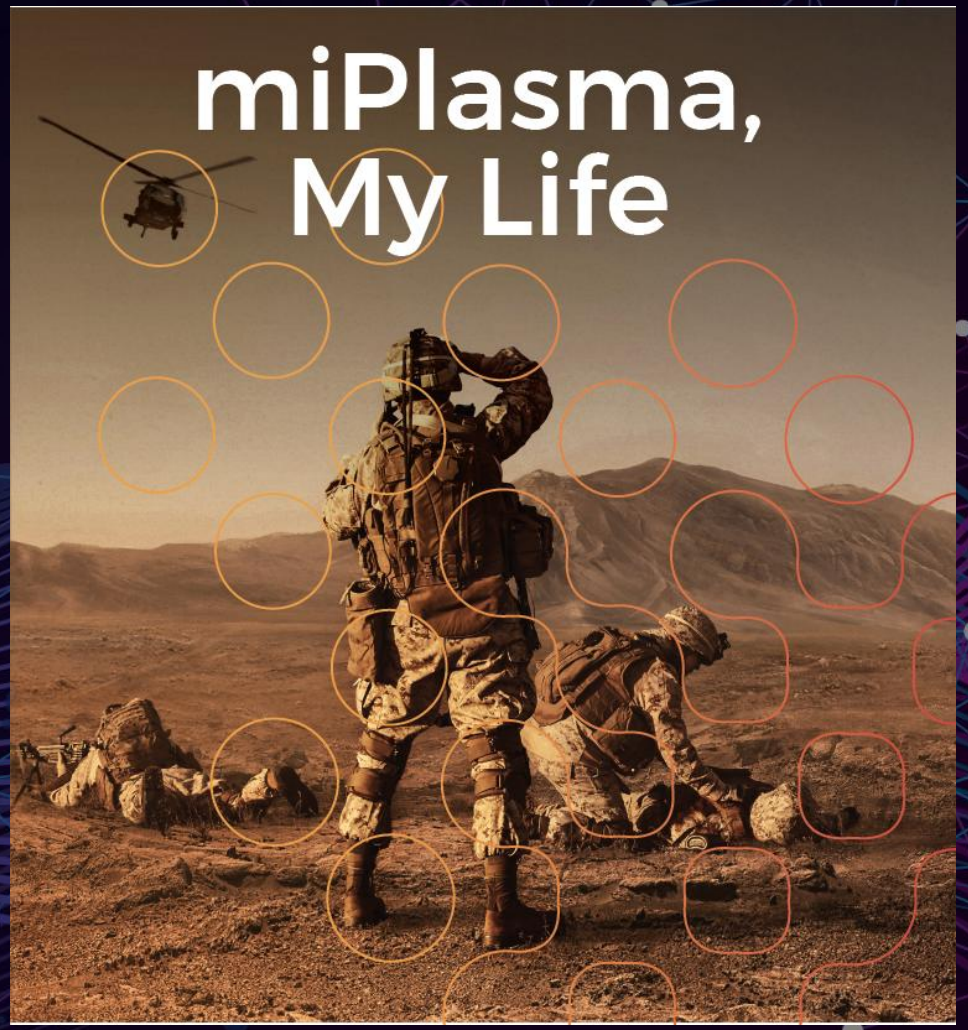
Spray Dried
Plasma
Production Facility
THIS WAY
velico®
The Future of Blood

Remapping the solution...



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#PlasmaEverywhere; Vision

1

Plasma as the new standard of pre-hospital resuscitation & hemorrhage control

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#PlasmaEverywhere; Vision

2

Available to the patient within 20 mins of injury

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1. Become Self-sufficient.
2. Advocate a new standard of care.
3. Prepare now.

velico®

#PlasmaEverywhere

Decentralized

Produced rapidly by existing blood center staff

No Freezers

Refrigerated up to 2 years or ambient storage for 1 year

No Glass or Waste

Robust and Ultra lightweight packaging

Rapid Rehydration

Able to be transfused within 2.5 minutes at point of injury

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