LUNALABS

Packaging for Improved Pharmaceutical Protection in Space

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2024 NASA HRP Investigators' Workshop

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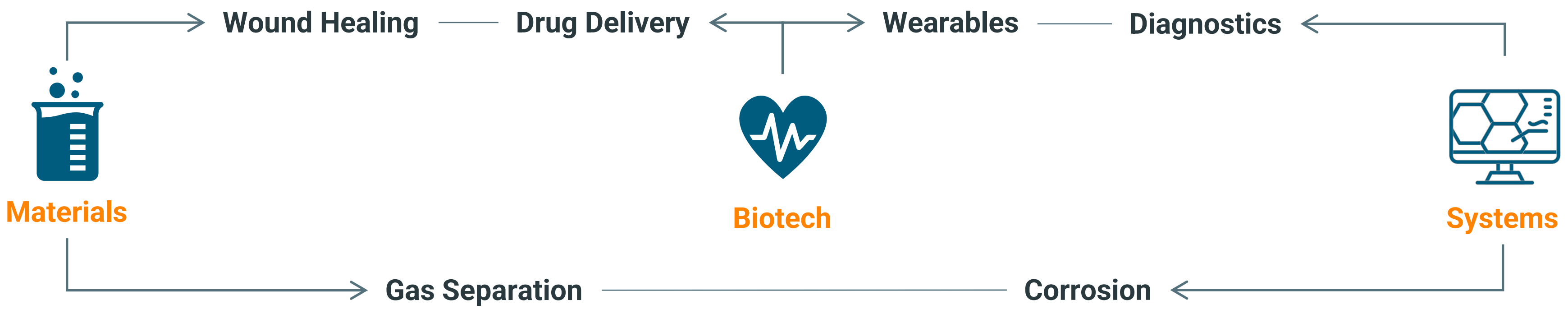
We develop products that increase the productivity of mission-driven organizations



Relevant Capabilities

PHARMACEUTICAL STABILITY TESTING

Luna Labs is developing **antibiotics formulated as chewable gummies**. The pharmaceuticals are taste-masked and stabilized within a chewable matrix to appeal to children.

PACKAGING DESIGN AND DEVELOPMENT

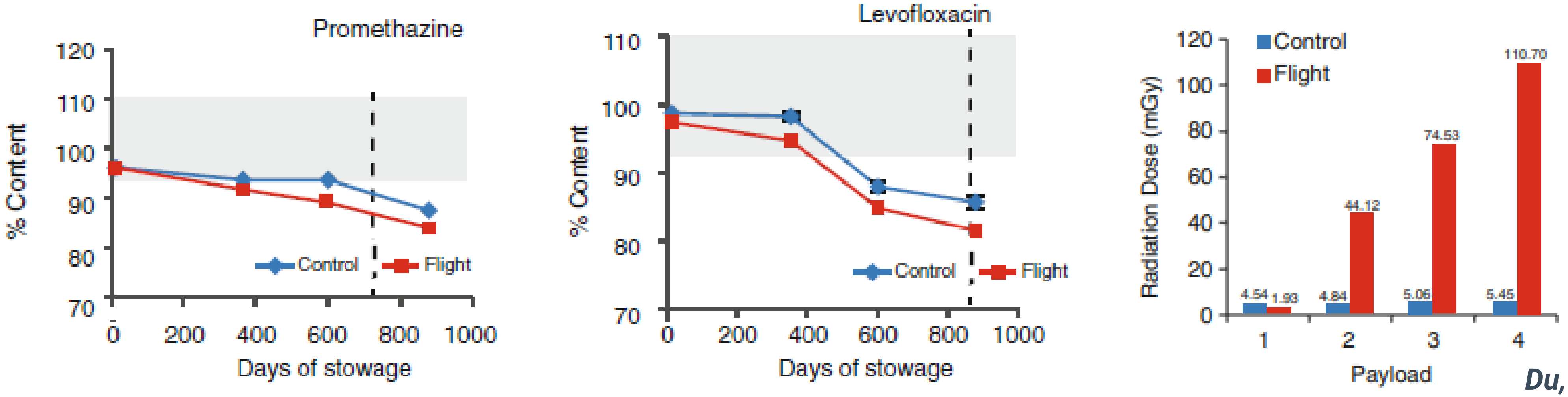
Luna Labs is developing a **low-cost, mechanical cap** designed to reduce biospecimen container failure caused by user mishandling.

MATERIALS SCIENCE AND ENGINEERING

Luna Labs is developing a biomechanically informed skin simulant. The **aramid nanofiber-reinforced composite material** is expected to enable standardized testing of non-lethal weapon safety.

A state-of-the-art pharmaceutical packaging solution for exploration missions is needed

- The availability of necessary pharmaceuticals to spaceflight crews is critical to mission success, and this need becomes more significant for long-duration exploration missions.
- The data available shows that the median risk of drug failure (USP acceptance thresholds) is **approximately 59% for a 2-year exploration mission** and **about 82% for a 3-year mission**.
- There is an **operationally derived need to repack several crew medications** to reduce costs to mass and volume, and **exposure to spaceflight conditions** may add additional risk.



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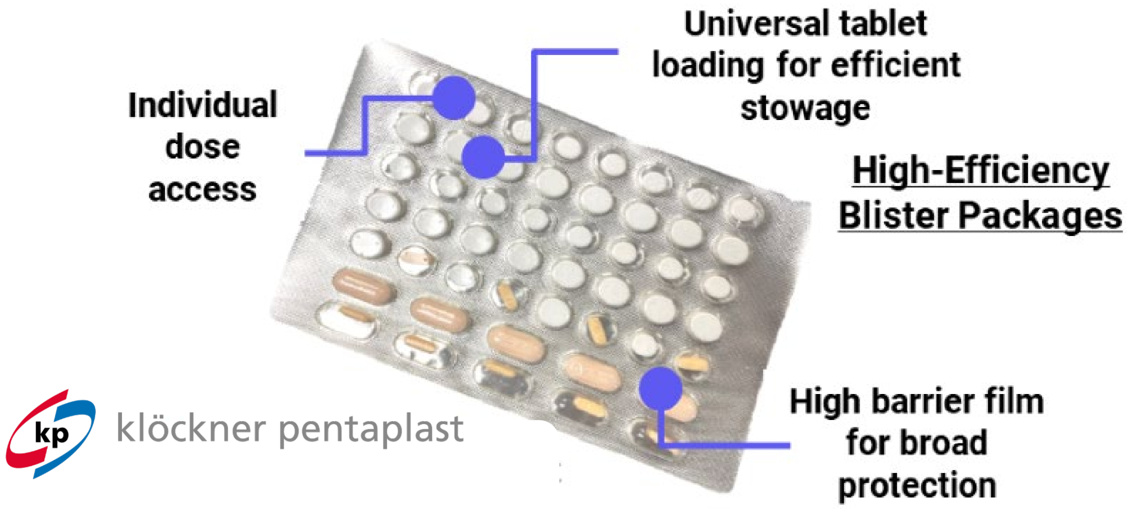
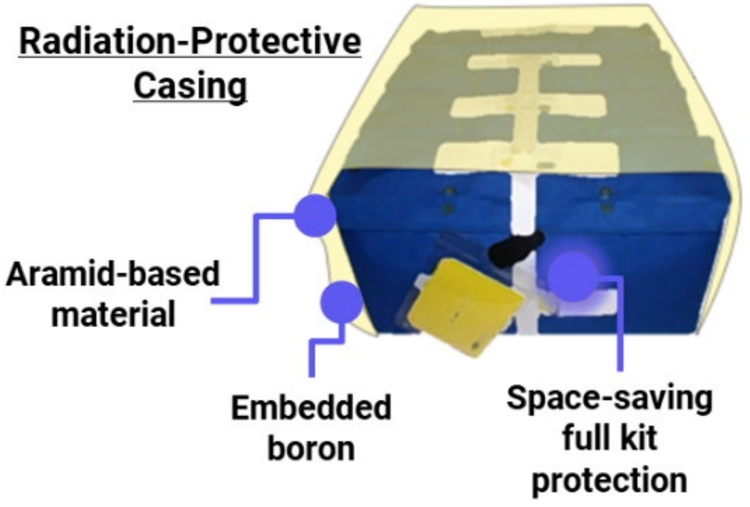
Luna Labs is developing a protective packaging system to improve pharmaceutical stability in space

The comprehensive packaging system includes two components:

- **High-efficiency blister packages** provide protection of repackaged solid doses *without the typical costs to mass and volume*.
- A protective **boron-containing, aramid-based composite material** will *reduce the expected radiation exposure* during spaceflight.





High Efficiency Blister Packages

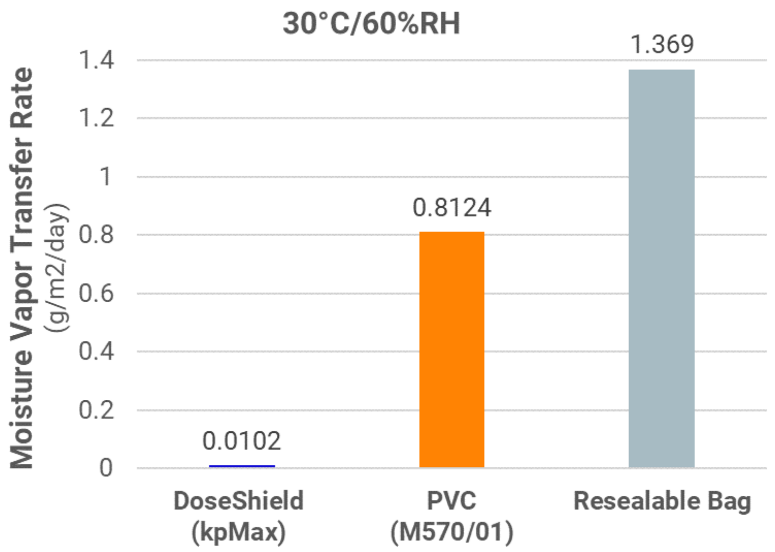
Representative pharmaceutical tablets were identified and studied to support packaging development

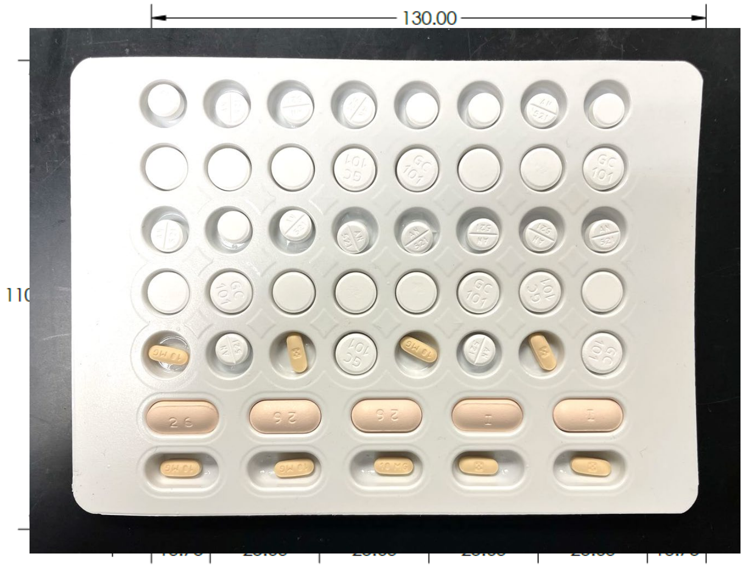
- Solid dose medications were identified based on **(1)** category of medication, **(2)** medications commonly flown and administered in space, and **(3)** demonstrated stability concerns in flight studies:
  - **Promethazine (PMZ)**
  - **Levofloxacin (LVF)**
  - **Acetaminophen (ACT)**
  - **Zolpidem (ZPM)**
  - **Ibuprofen (IBU)**
  - **Levothyroxine (LVT)**
  - **Amoxicillin/Clavulanate (AMC)**

Identify mechanisms of instability (e.g., moisture, oxygen) → Design packaging to provide the requisite protection → Demonstrate efficacy of the packaging

Initial blister cards were designed and prototyped for tablet repackaging and evaluation

- A barrier film material was identified to enable **protection of a broader range of pharmaceutical products** due to low permeability to moisture *and* oxygen.
- Initial blister card designs included round and oblong cavities in a layout that allowed for **maximized loading of medications** compared to standard blister card formats.

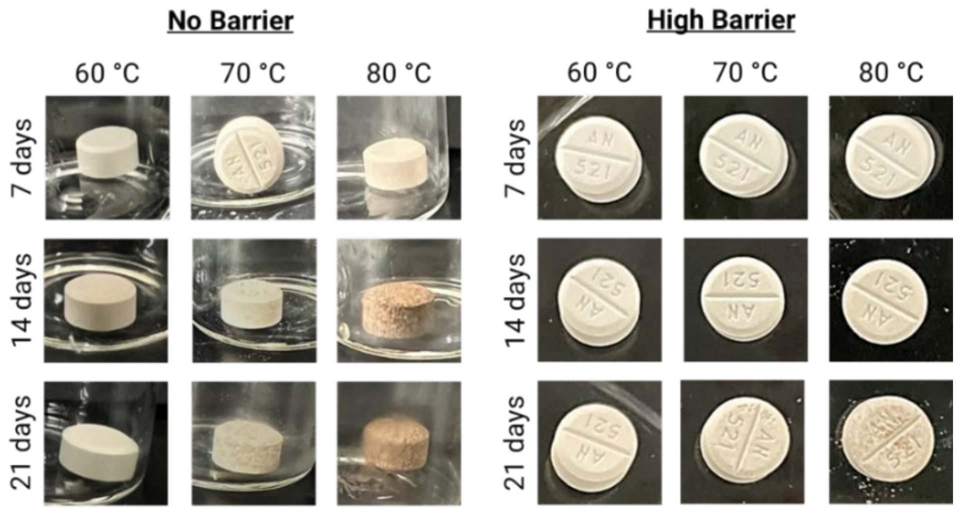


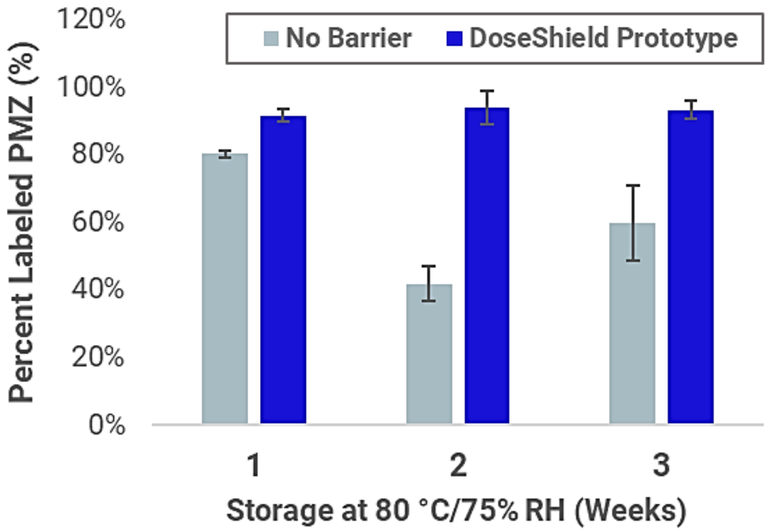


Pharmaceutical stability within the packages was studied under accelerated conditions

- To demonstrate the ability of the packages to provide solid dose protection, accelerated – **thermal (60, 70, 80 °C) and hydrolytic (75% relative humidity)** – studies were performed for 'No Barrier' samples and 'High 'Barrier', repackaged PMZ tablets.

- After the exposure, tablets removed from Luna Labs' blister cards exhibited **fewer physical changes,** and **greater PMZ content was maintained** at each condition.

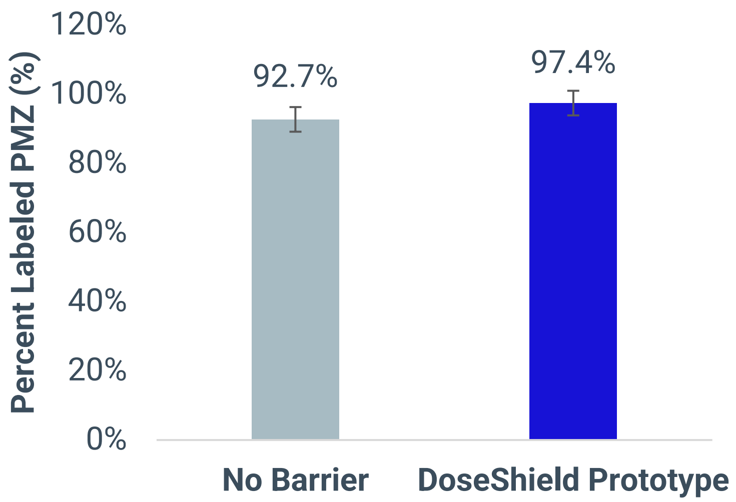


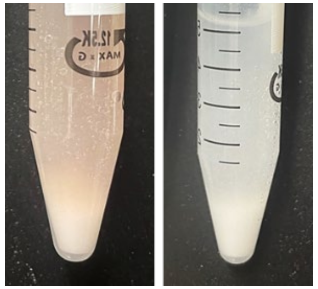


Pharmaceutical stability within the packages was studied under accelerated conditions

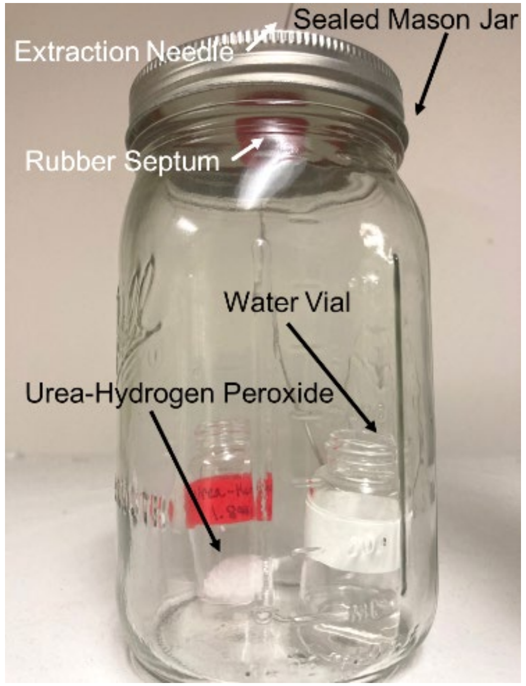
- To demonstrate the ability of the packages to provide solid dose protection, accelerated – **oxidative (approximately 0.64 mg H_2O_2)** – studies were performed for 'No Barrier' samples and 'High 'Barrier', repackaged PMZ tablets.

- Tablets removed from Luna Labs' blister cards exhibited **fewer physical changes** and **greater remaining PMZ content** after the exposure.





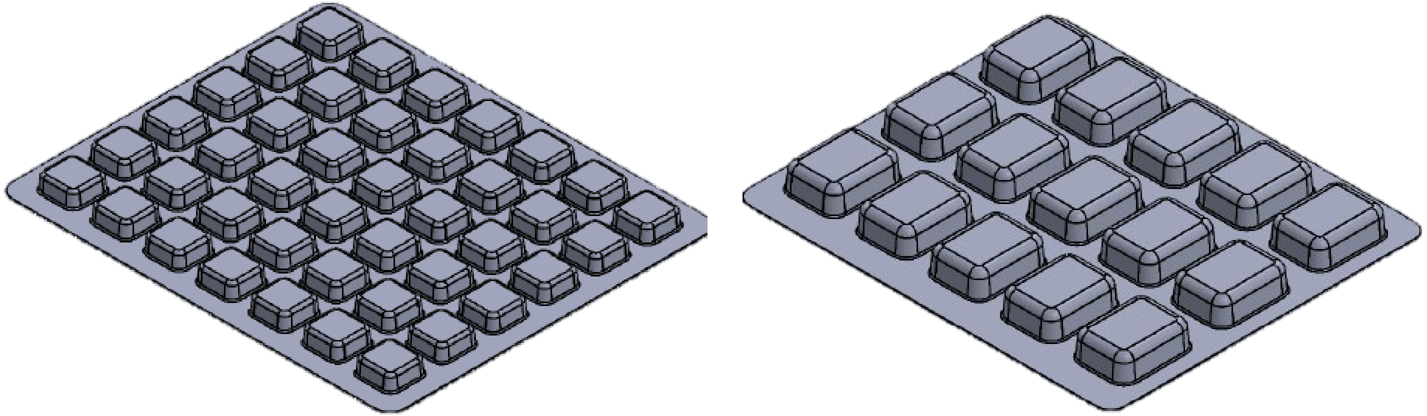
No Barrier DoseShield Prototype



Chamber to generate H_2O_2 exposure.

Ongoing work is expanding development to support repackaging implementation

- Additional blister card formats have been designed to support a **wider range of pharmaceuticals** with maintained efficiency.
- **Repackaging processes** are under development.
- Baseline and 6-month testing has been performed within an ongoing **two-year efficacy study** (25 °C, 60% relative humidity) evaluating **expanded solid dose properties**.



Additional blister card formats to improve versatility.

Representative two-year study sample set.

Benchtop heat-seal press.

Space Radiation Barrier

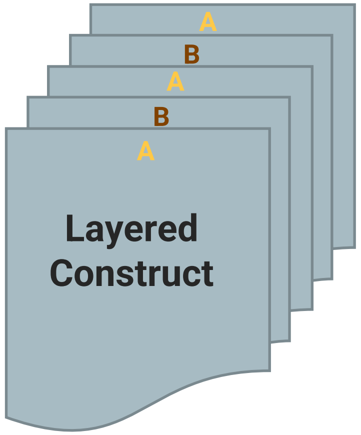
Boron-containing composite materials are also under development

- Aramid-based materials have demonstrated **shielding against heavy ion radiation exposure** comparable to polyethylene (PE).
- Materials containing boron have shown the ability to **absorb the low energy neutrons** produced during shielding.
- Various materials and **layered constructs (20 mm)** have been fabricated for evaluation.

Aramid-based film.

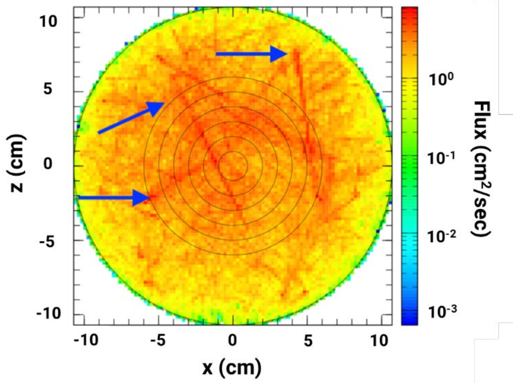
Film with boron incorporated.

Aramid pulp board.

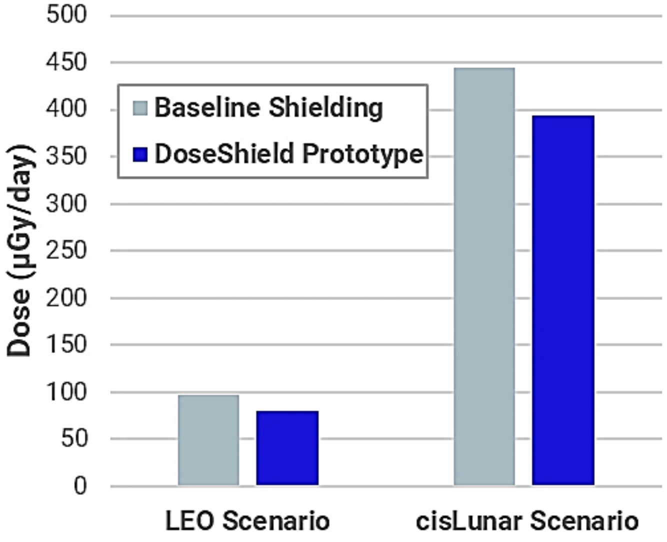


Collaboration with Prof. Jeff Chancellor supported evaluation of space radiation shielding potential

- Radiation shielding was evaluated via simulation of the non-homogenous space radiation environment with the shielding approximately equivalent to crew vehicles (e.g., the SpaceX Dragon capsule) for two scenarios:
  - Spacecraft in the **Low Earth Orbit** environment (LEO) -
    - The dose measured in the scoring volume for Luna Labs' material was **16.8% less than a baseline** with no protective barrier.
  - Spacecraft in the **cisLunar** -
    - The dose measured in the scoring volume for Luna Labs' material was **11.5% less than a baseline** with no protective barrier.

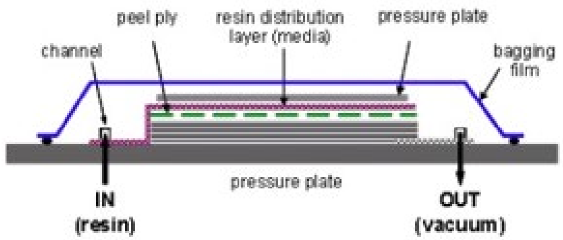


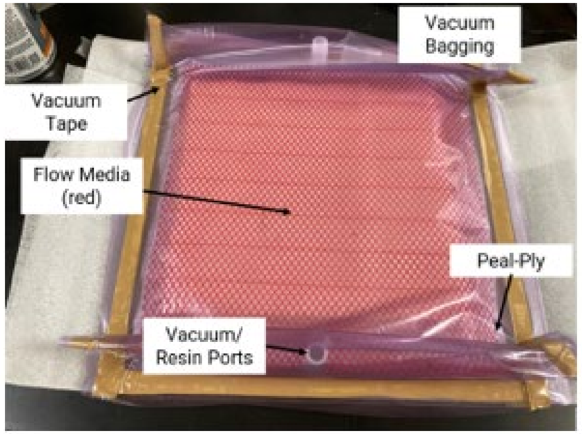
Geometry for Monte Carlo calculations.



Upcoming work will include experimental evaluation of space radiation shielding potential

- Additional fabrication techniques are being evaluated to allow scaled production.
- Simulation of the non-homogenous space radiation environment is being utilized to **optimize material formulation and construction** (e.g., thickness, layers), and the final protective casing will be established.
- Capabilities at the **NASA Space Radiation Laboratory** will be utilized to:
  - Experimentally evaluate shielding potential.
  - Demonstrate the protective effects on:
    - Representative solid dosage forms
    - **Additional dosage forms**





Vacuum-assisted resin transfer (VARTM) lay-up.

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