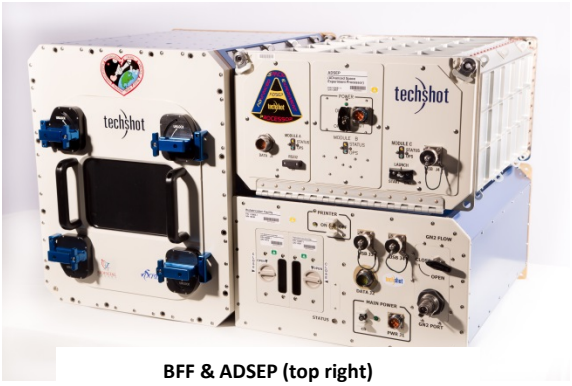
The Apollo program captured and united the imaginations of the people of this nation and the world. In an era when commercial companies compete to do in space what previously was only thought possible by sovereign nations, the addition of BFF to the ISS is a ***"Moonshot for the 21st Century****."*

About the 3D BioFabrication Facility (BFF)

The 3D BioFabrication Facility (BFF) is the first-ever 3D printer capable of manufacturing human tissue in the microgravity condition of space. Utilizing adult human cells (such as pluripotent or stem cells), the BFF can create viable tissue in space through technology that enables it to precisely place and build ultra-fine layers of bioink – layers that may be several times smaller than the width of a human hair – involving the smallest print tips in existence.



BFF & ADSEP (top right)

The first American bioprinter in space, BFF will be the most capable system of its kind operated by any nation aboard the International Space Station (ISS).

Why bioprint in space?

Tech demonstrator BFF in parabolic flight

While researchers have seen some success with the 3D printing of bones and cartilage, the manufacture of soft human tissue, such as blood vessels and muscle, has proven more difficult. On Earth, when attempting to print with soft, easily flowing biomaterials that better mimic the body's natural environment, tissues collapse under their own weight – resulting in little more than a puddle. But if these same materials are used in space in a microgravity environment, 3D-printed soft tissues will maintain their shape.

Without proper conditioning, space-printed tissues also would collapse if immediately returned to Earth. Launching along with BFF is a Techshot-developed cell-culturing system that strengthens the printed tissue over time, to the point where it becomes a viable, self-supporting tissue that will remain solid once back in the Earth's gravity. Whereas the tissue printing process may take less than a day, the strengthening process will likely take 12 to 45 days, depending on the tissue.

How and when will it be launched into space?
During mid-2019, BFF will be launched aboard the commercial uncrewed SpaceX CRS-18 cargo mission from Cape Canaveral for delivery to the ISS. Once aboard the orbiting complex, it will be installed in the European laboratory module known as Columbus.

Defining success for the mid-2019 launch
The first stay of BFF aboard the ISS will last for several months (or longer). Techshot will test the system by attempting very simple prints of cardiac-like tissue. The tissues will be conditioned in space within a cell culturing cassette inside Techshot's ADvanced Space Experimenter Processor (ADSEP), mounted nearby BFF aboard the station. The tissues must remain in space in the cassettes for several weeks to grow and mature enough to survive the stresses of returning to Earth's gravity. Therefore, the main goal of the first test prints is the return of live space-printed tissue to Earth. At some point it likely will be brought back to Earth and improved with any modifications that may be needed before relaunching for the next round of tests in space.

The timeline
The first phase for BFF, which could last about two years, will involve creating test prints of cardiac-like tissue of increasing thickness. The next phase, where heart patches are manufactured in space and evaluated on the ground (under a microscope and in animals, but not likely in humans yet), could last through 2024. The manufacturing of whole organs in space would not likely be attempted until at least 2025.

The path to regulatory acceptance of replacement human organs that were manufactured in space is anticipated to be very long – taking perhaps 10 years. Concurrent with Techshot's own plans, the company also will be leasing BFF to other research teams who may have more aggressive timelines for their projects.

Also, BFF may have a role in deep space exploration, where it could be used to make food items, or function as a compounding pharmacy – enabling the remote formulation of drugs optimized for each crew member.

Challenges, barriers moving forward
There are many. But it can be done, and the potential benefits far outweigh the challenges. It will require patience. But Techshot has been building space research equipment for 30 years and understands very well how to continually improve processes. Techshot has several other research devices (not related to BFF) already onboard the space station. And nScrypt makes the best 3D printers in the world. Its SmartPump™ Micro-Dispensing tool head enables the most precise placement of bioink.

Besides the technical challenges that must be overcome, Techshot expects years of work to achieve regulatory approval for its space-manufactured tissue. The company wants BFF to benefit patients on Earth as quickly as possible, which is why, after its own initial tests are complete, Techshot will allow other research groups to use it in space. The prospect of creating whole organs in space is real – but still years away.

Scalability … producing enough organs in space to make an impact on Earth
This process is quite scalable. While it is too soon to speculate on specific numbers, someday BFF stands to make an impact on organ transplant waiting lists. If the system advances as planned, it may be producing viable organs and tissues in the next five or six years. One potentially limiting factor in scale-up is the availability of rack space in orbiting vehicles. The ISS is near capacity.

But Techshot is not limited to the ISS. It already is exploring options with commercial enterprises that are working on creating microgravity laboratories for research.

BFF can offer an array of medical breakthroughs in the future
The long-term success of BFF as a human organ manufacturing system brings an array of prospective medical breakthroughs, including:

- reducing the organ donor shortage (there are about 113,000 people on organ transplant waiting lists)
- creating patient-specific replacement tissues or patches
- the possibility of transplant recipients receiving organs comprised of their own stem cells, thus reducing likelihood of rejection, and reducing long-term costs associated with a lifetime of anti-rejection drugs, and perhaps additional transplants
- eliminating the requirement that someone must first die in order for another person to receive a new heart or other organ

Affordability of space-produced organs
Though years away, the ideal candidate for an organ manufactured in space will be someone who's alternative treatment plan includes a lifetime of expensive anti-rejection drugs for a donor organ, many of which have their own unwelcome consequences. Some patients also require multiple transplants over their lifetime. An organ manufactured in space from the patient's own stem cells will not require anti-rejection drugs. Therefore, the overall lifetime cost for a single transplant is expected to be lower for the patient receiving an organ manufactured in space than the alternative.

A personal stake behind the science
nScrypt CEO Ken Church has a very personal stake in BFF. Twenty-four years ago his daughter was born with one lung and was given a 10 percent chance of survival. She survived, and today lives an active and full life despite her missing lung. "But why," Church said a million times, "can't we make her another lung."

Twenty-four years ago, of course, Ken's question was a non-starter. Creating a lung was impossible. Today, the answer to the question is much different. While assembling a human lung or other organ is still years away, BFF presents a roadmap.

"At a conceptual level, it's not that tricky," said Church. "This BFF team knows how to get there. But it will require baby steps and patience. I have no doubt someday BFF will provide someone like my daughter with a second lung."

Who's behind the creation of BFF?
Two high-tech companies have teamed up to develop the technology capable of manufacturing human organs and tissue on orbit: Techshot Inc., a commercial developer and operator of spaceflight equipment for more than 30 years; and nScrypt Inc., a manufacturer of the world's most advanced industrial 3D bioprinters and electronics printers. A small bioink startup, Biofícial Organs, also was consulted on the project.

Techshot: Techshot Inc., has been developing new technologies for the aerospace, defense and medical industries since 1988. Its devices have flown aboard parabolic-flight aircraft, sub-orbital rockets, space shuttles, the Northrop Grumman Cygnus, the SpaceX Cargo Dragon and the International Space Station. Its Space Act Agreement with NASA permits the company to commercially operate its equipment aboard the station. Since 2015 the Techshot-designed and built Bone Densitometer has been conducting X-ray evaluations of mice in space for biopharma companies such as Novartis and Eli Lilly. Its Multi-use Variable-gravity Platform has been aboard the station since April 2018. Techshot is headquartered in Greenville, Indiana and maintains an office at the Kennedy Space Center in Florida. http://www.Techshot.space

nScrypt: Founded in 2002 and headquartered in Orlando, Florida, nScrypt designs and manufactures award-winning, next-generation, high-precision Micro-Dispensing and Direct Digital Manufacturing equipment and solutions for industrial applications, with unmatched accuracy and flexibility. Serving the printed electronics, electronics packaging, solar cell metallization, communications, printed antenna, life science, chemical/pharmaceutical, defense, space, and 3D printing industries, its equipment and solutions are widely used by the military, academic and research institutes, government agencies and national labs, and private companies.

nScrypt's BAT, the world's first commercially available bioprinter, which was developed under a contract with the Defense Advanced Research Projects Agency (DARPA), won R&D Magazine's 2003 Top 100 award. https://www.nscrypt.com