

2011 Military Health System Conference

Armed Forces Institute of Regenerative Medicine Clinical Trials

The Quadruple Aim: Working Together, Achieving Success

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26 January 2011



USAMMDA



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(Re)Generating the Future of Therapy



26 JAN 2011

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AFIRM

26Jan 2011

AFIRM Mission



- Discover, develop, and translate regenerative medicine technologies having both near term and far-term translation potential



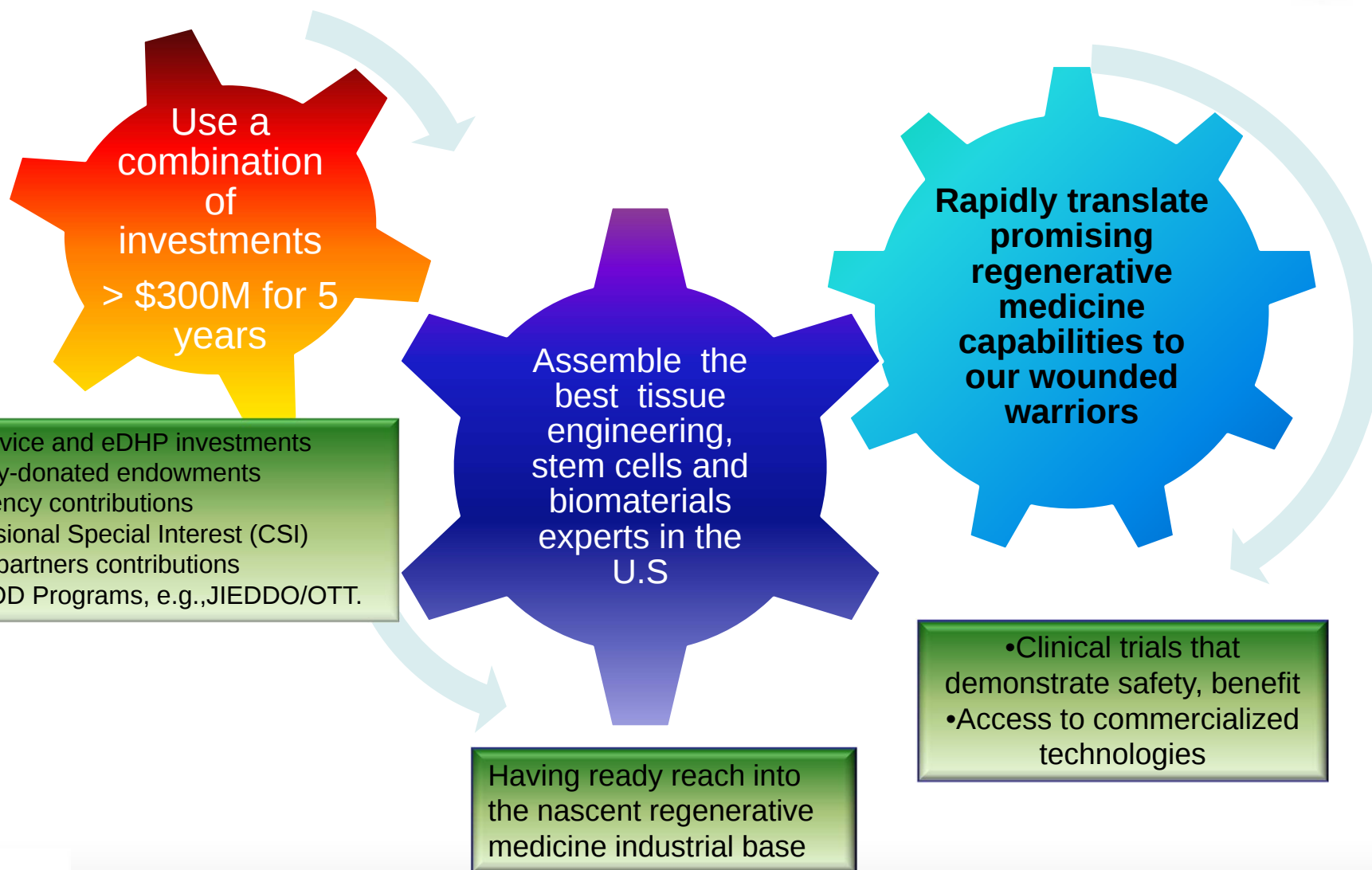
- To provide cutting-edge medical capabilities to heal and reset our warriors who have catastrophic traumatic injuries and disabilities



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AFIRM Strategy



AFIRM Partners & Proud Sponsors



Top US Institutes & Researchers

(2001-2007)



US Rank	University	In AFIRM
1	Harvard	Y
2	MIT	Y
3	Univ. Pittsburgh	Y
4	Columbia Univ.	
5	Tufts	Y
6	Georgia Tech	Y
7	Rice	Y
8	Stanford	Y
9	Case Western	Y
10	Johns Hopkins	Y

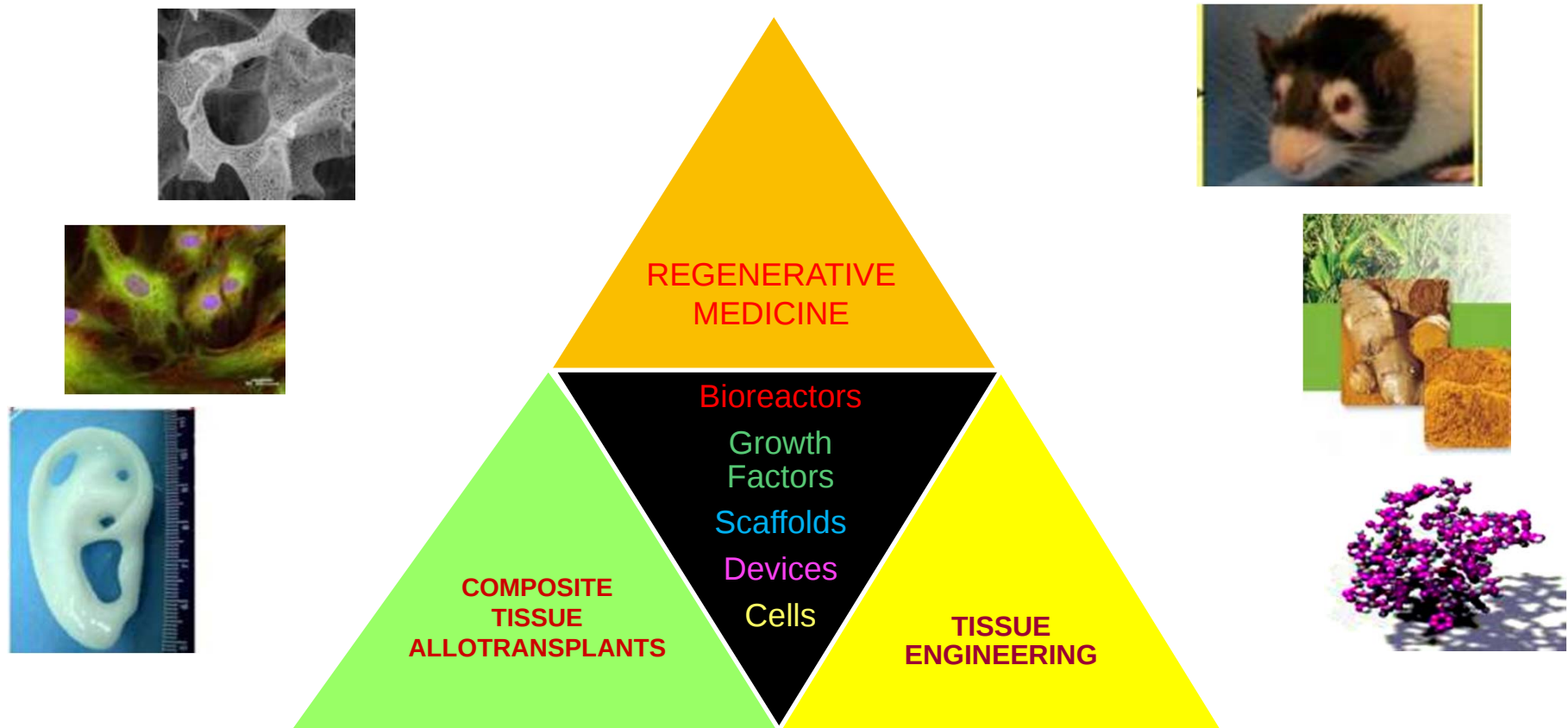
US Rank	Researcher	In AFIRM
1	David Kaplan	Y
2	Rocky Tuan	Y
3	Robert Langer	Y
4	Gordana Vunjak-Novakovic	
5	Johnny Huard	Y
6	Michael Longaker	Y
7	Jeffrey Gimple	Y
8	Joseph Vacanti	Y
9	Anthony Atala	Y
10	Antonios Mikos	Y

From: World Technology Evaluation Center Report: International Assessment of Research and Development in Stem Cells for Regenerative Medicine and Tissue Engineering, MAR 2008



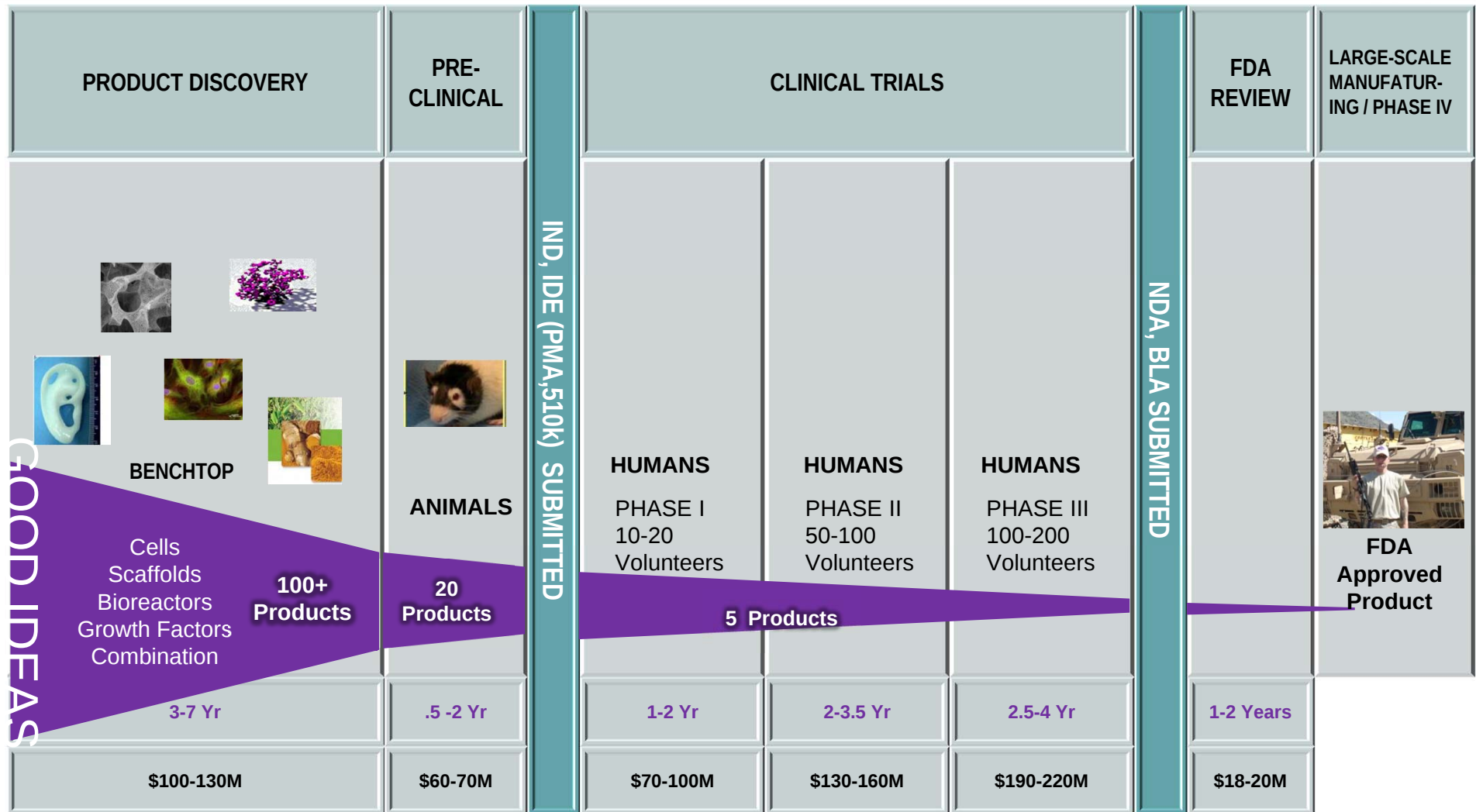
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Approaches to Regeneration



All major scientific approaches to tissue regeneration are utilized in the development of regenerative therapies for the wounded service members

Regenerative Medicine Product Development



Ref. AFIRM 2010. Estimated Time in Stage - Total = 10-20.5 Years

~~ Estimated Cost per Stage - Total = \$568-700M

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To Heal our Wounded Warriors



Five Areas of Emphasis



*Cranio-Facial
Reconstruction*



Burn Repair



Healing Without Scarring



Compartment Syndrome



*Limb and Digit Salvage and
Reconstruction*



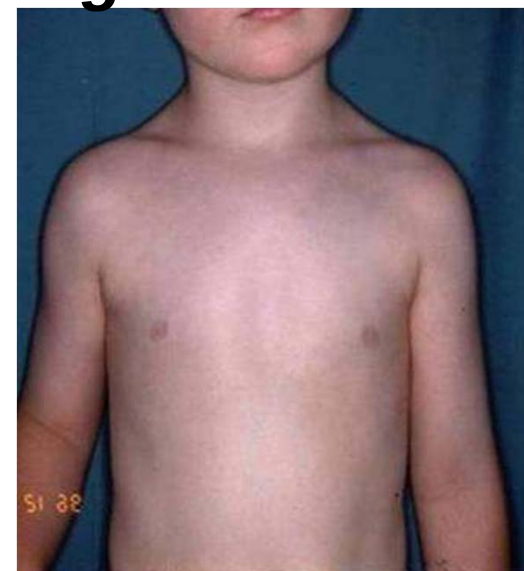
FY 2010 Clinical Trials

Cell Spraying to Reduce Burn Scarring & scar revision

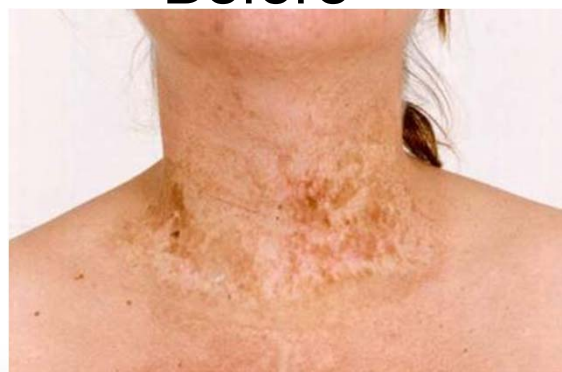


Before

ReCell
Avita Medical



After



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FY 2010 Clinical Trials

Hand Transplants



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Face Transplants



Wake Forest -
Pittsburgh
Consortium
(WFPC)

Rutgers-
Cleveland Clinic
Consortium
(RCCC)

FY 2011 Clinical Trials Engineered Skin



Lonza

Autologous Engineered Skin



Rutgers-
Cleveland
Clinic
Consortium
(RCCC)



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Stratatech

Allogeneic Engineered



Wake
Forest -
Pittsburgh
Consortium
(WFPC)

FY 2011 Clinical Trials



Fat Injections to Fill Facial Defects

Before



Clinical trial uses patient's own fat and fat derived stem cells for filling in dents in the face

After



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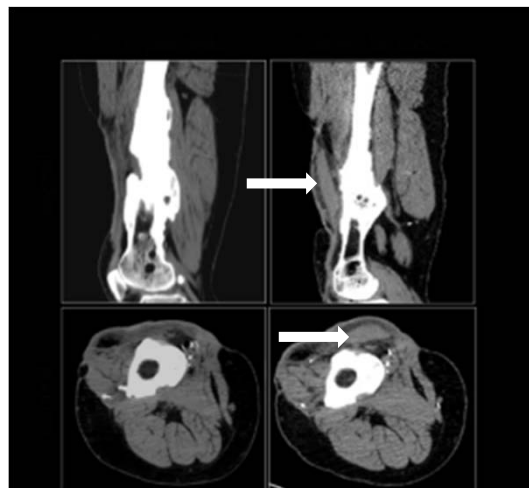
Funded by DOD Health Affairs Biotechnology Initiative and DHPE



FY 2010 Clinical Trials



Muscle Regeneration



CT scan showing 10% increase in quadriceps mass (white arrow) at 4 months post surgery.



Before



After



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AFIRM – Industry Partnership



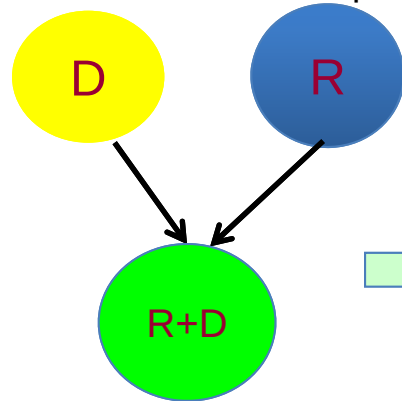
- Expertise in product development, marketing, regulatory, manufacturing
- Resources for clinical trials
- Licensing technology or Financial investment
- Provide a mechanism to advance combat casualty care
- Studies focus on questions of interest to the military but most of the products have commercial application
- Advances improve both military and civilian care



Other Promising Products on the Horizon

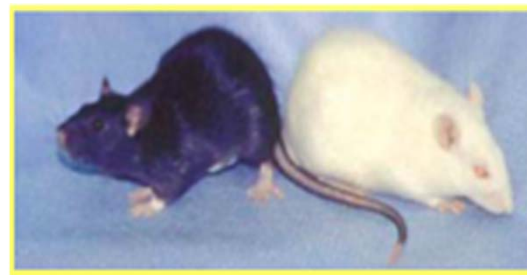


Tissue Donor Cell Transplant Recipient Cell



Chimeric Cell

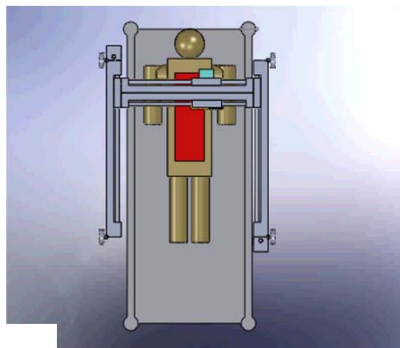
Transplantation Tolerance



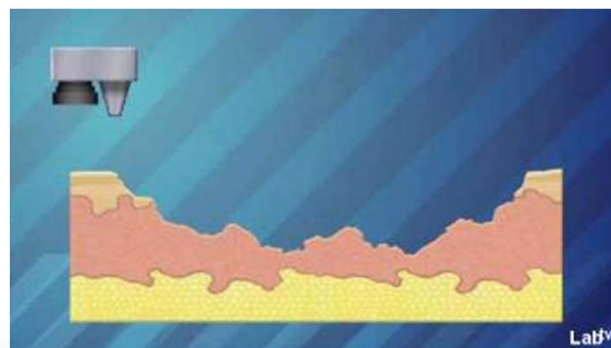
Mixed Allogeneic Chimera

Rutgers-Cleveland Clinic Consortium (RCCC)

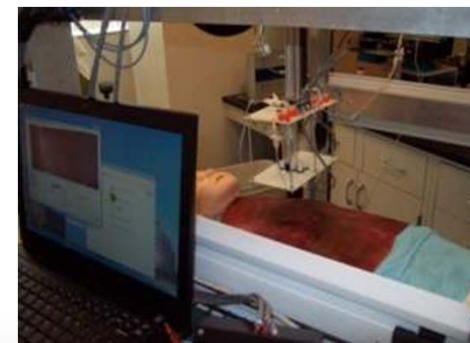
LEXMARK



Organogenesis Inc.
LIVING TECHNOLOGY



Skin Printer



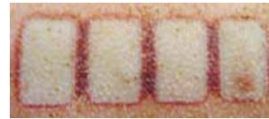
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Wake Forest - Pittsburgh Consortium (WFPC)

Other Promising Products



- ♦ Burn Treatment with **P12** peptide



control



untreated

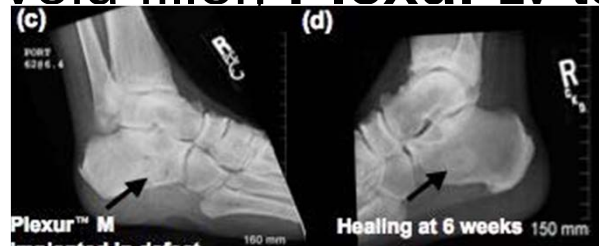


P12 treated

- ❖ Burn Treatment with **KeraHeal**, keratin based gel

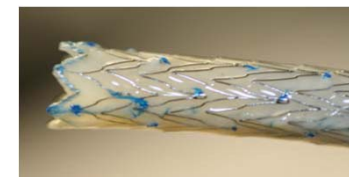
KeraNetics

- ❖ Injectable bone void filler, **Plexur-LV** to repair cranial and long bone defects.

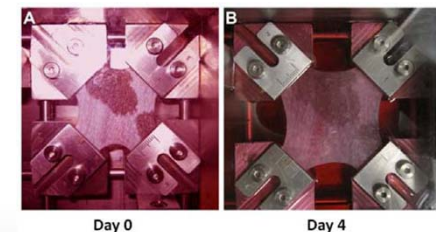


OSTEOTECH

- ❖ Fracture resistant **tissue stent** grafts to repair vascular trauma



- ❖ **Skin bioreactor**, in vitro tissue expander



For additional Information on AFIRM

Please contact:



U.S. Army Medical Materiel Development Activity



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LEST WE FORGET WHY WE ARE HERE



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