

Exportinitiative Gesundheitswirtschaft

Australia's Health Innovation Pipeline – Clinical Trials Capabilities in Down Under

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CMO

20th April 2023 – Webinar



Bundesministerium
für Bildung
und Forschung



AHK
Deutsch-Australische
Industrie- und Handelskammer
German-Australian Chamber
of Industry and Commerce

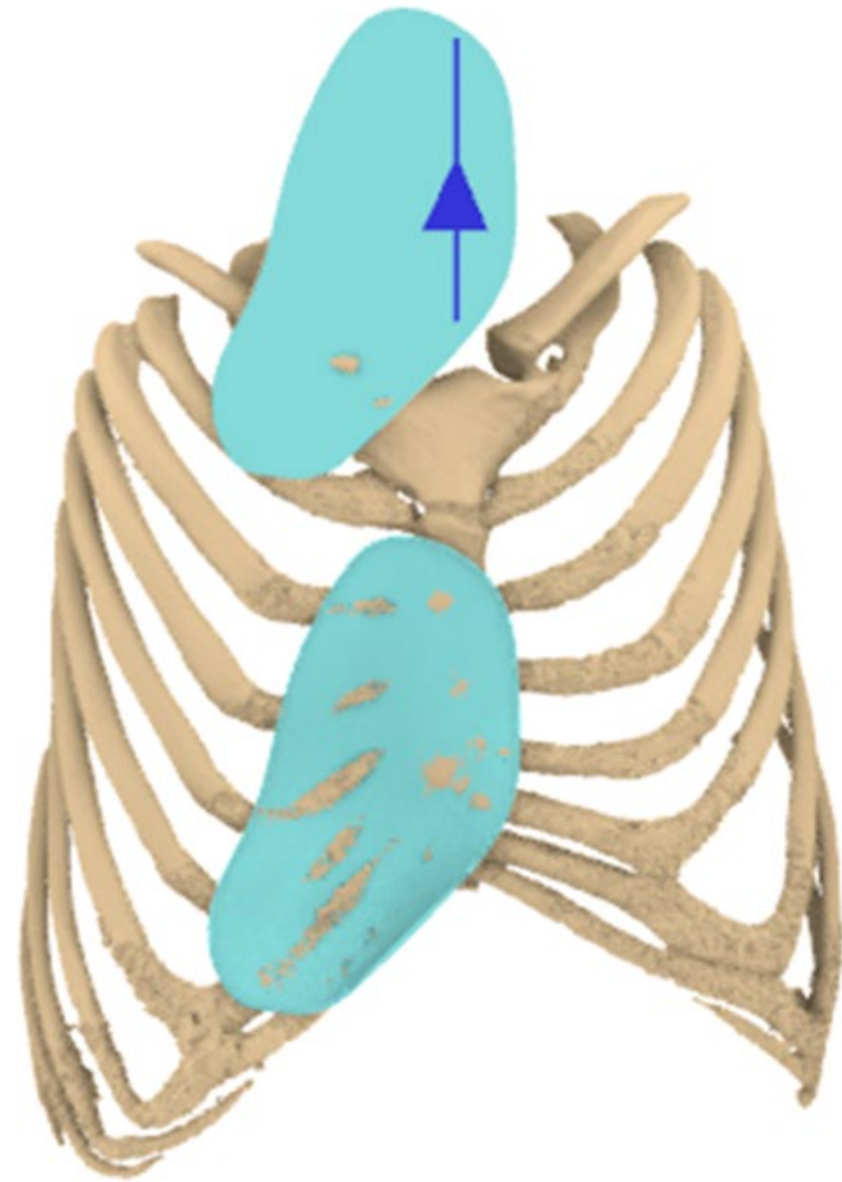




BellaSeno

- We manufacture **fully resorbable PCL implants** for hard- and soft tissue regeneration using our **proprietary 3D printing technologies**
- Located in **Leipzig, Germany** and **Brisbane, QLD, Australia**.
- BellaSeno was founded in 2017 based on **technology developed in Queensland**.
- **First-in-Human in 2020 in Brisbane QLD**

Unmet Medical Need



Pectus Excavatum



Ruptured Breast Implant



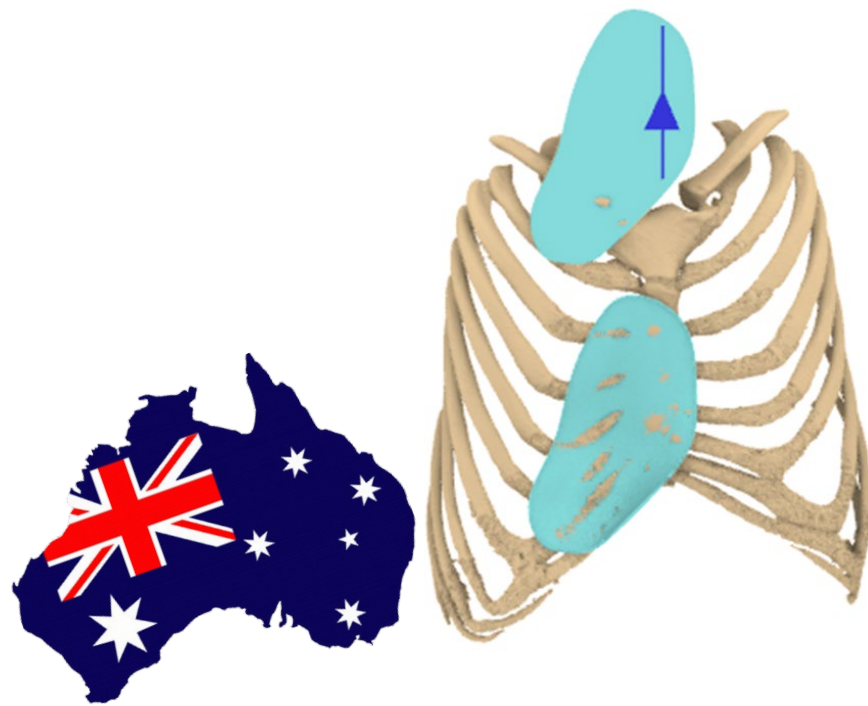
Critical Size Bone Defect

Our innovative scaffold solutions meets all 3 Medical Needs



Resorbable, Regenerative Flexible or solid Scaffold technology enabled by Own IP

Soft Tissue Reconstruction



Pectus Excavatum Camouflage

Custom-Made

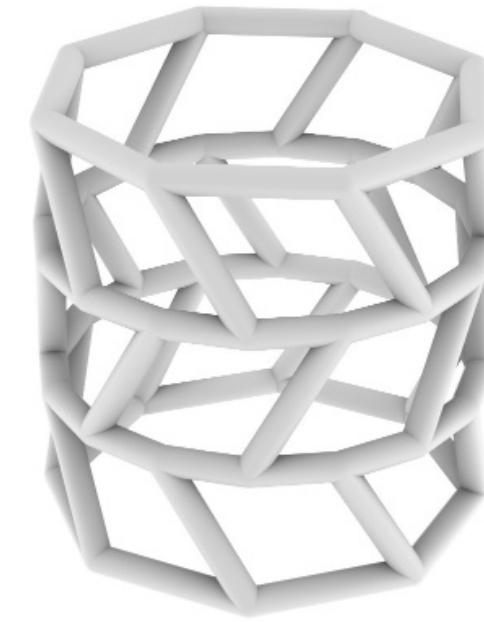


Breast Reconstruction

Custom-Made

Catalogue

Hard Tissue Reconstruction

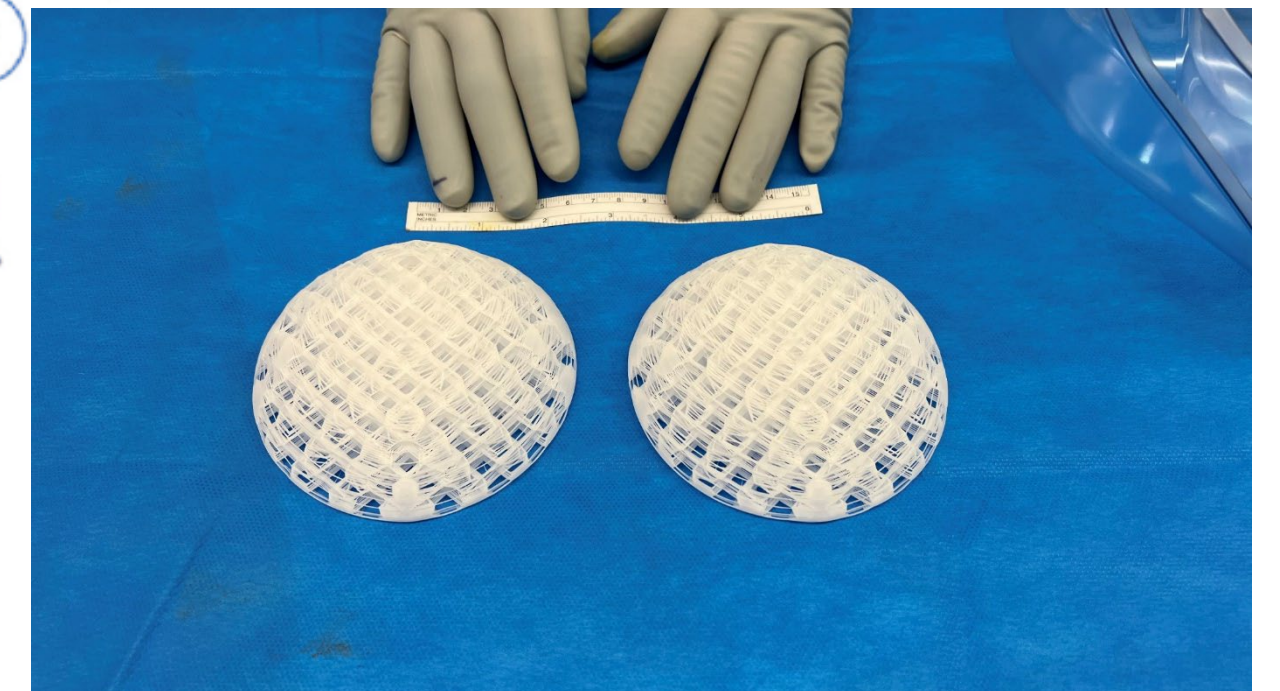
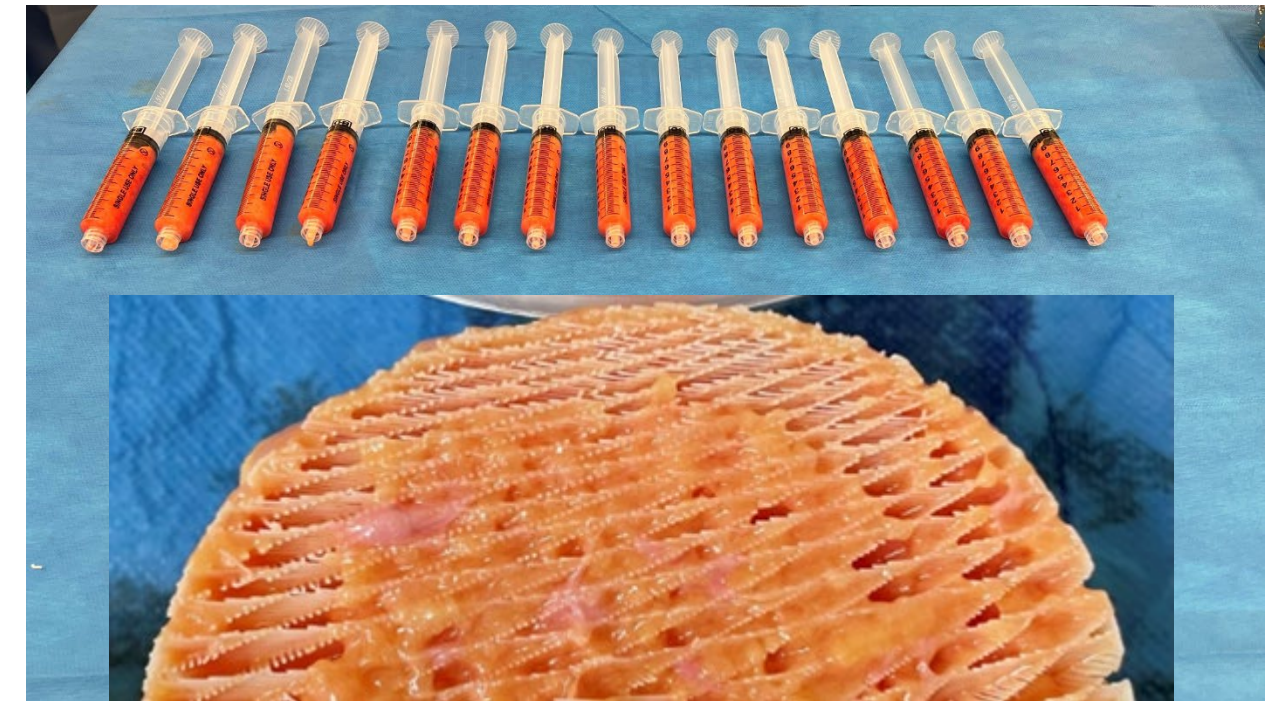
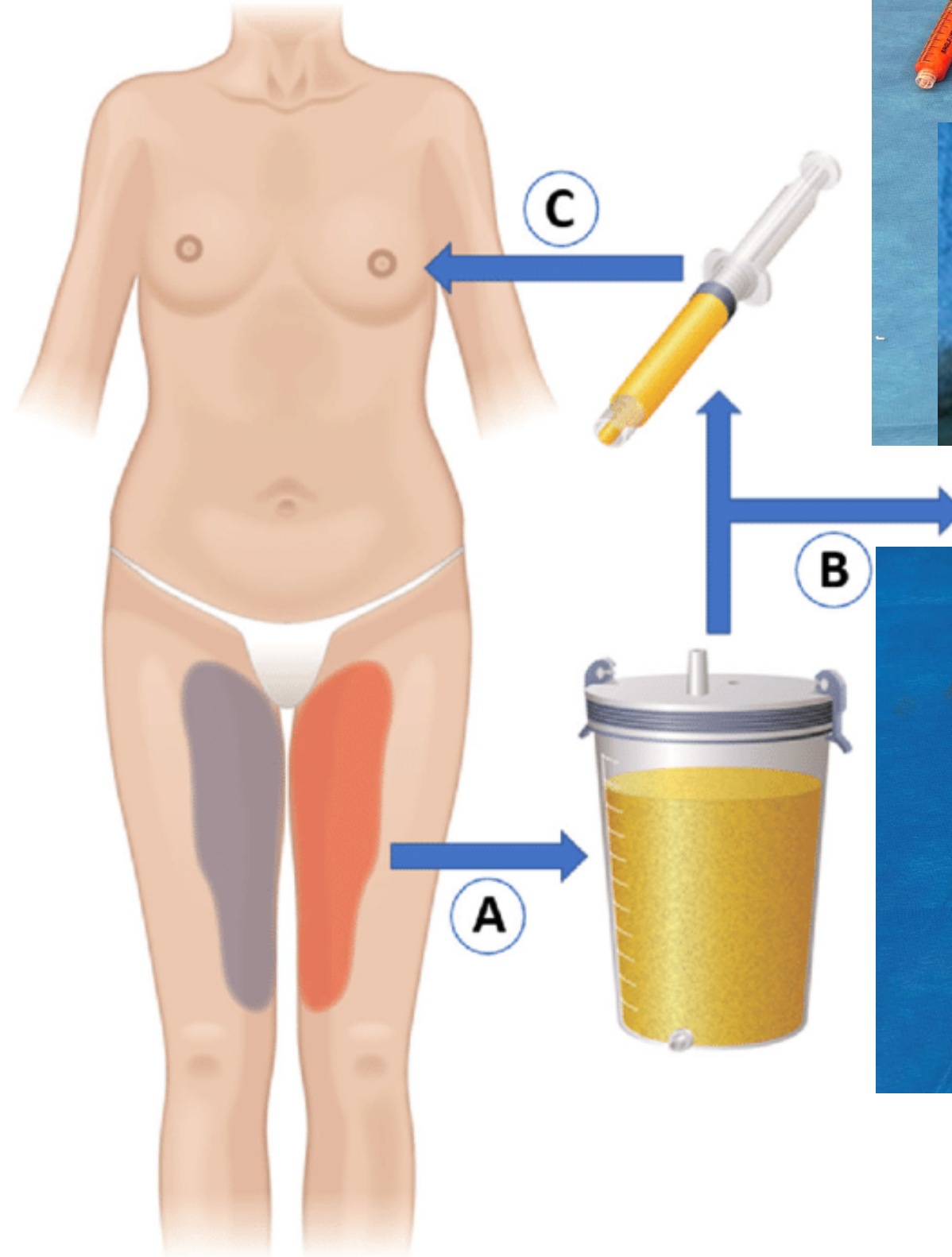
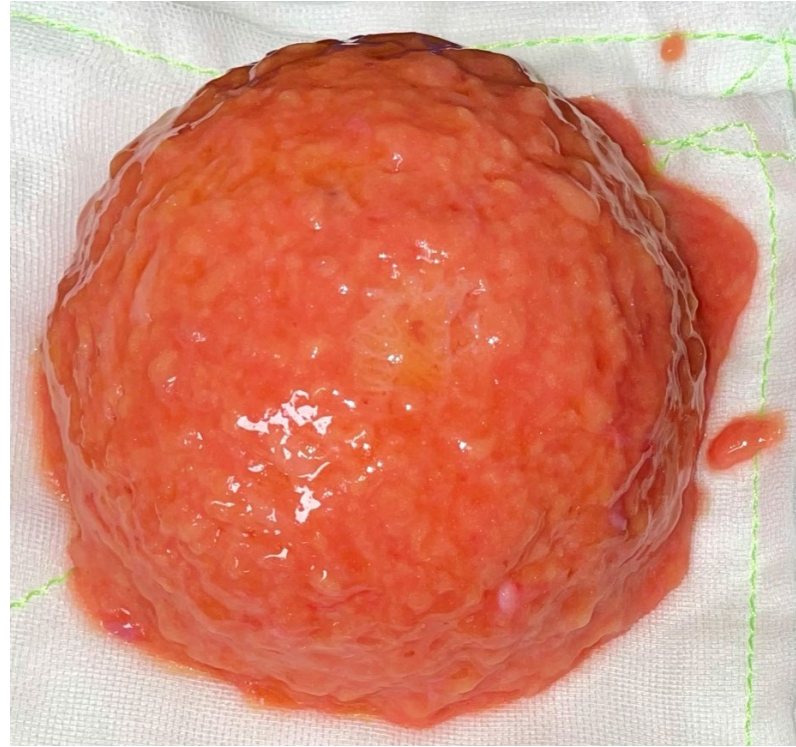


Segmental/Partial Bone Defects

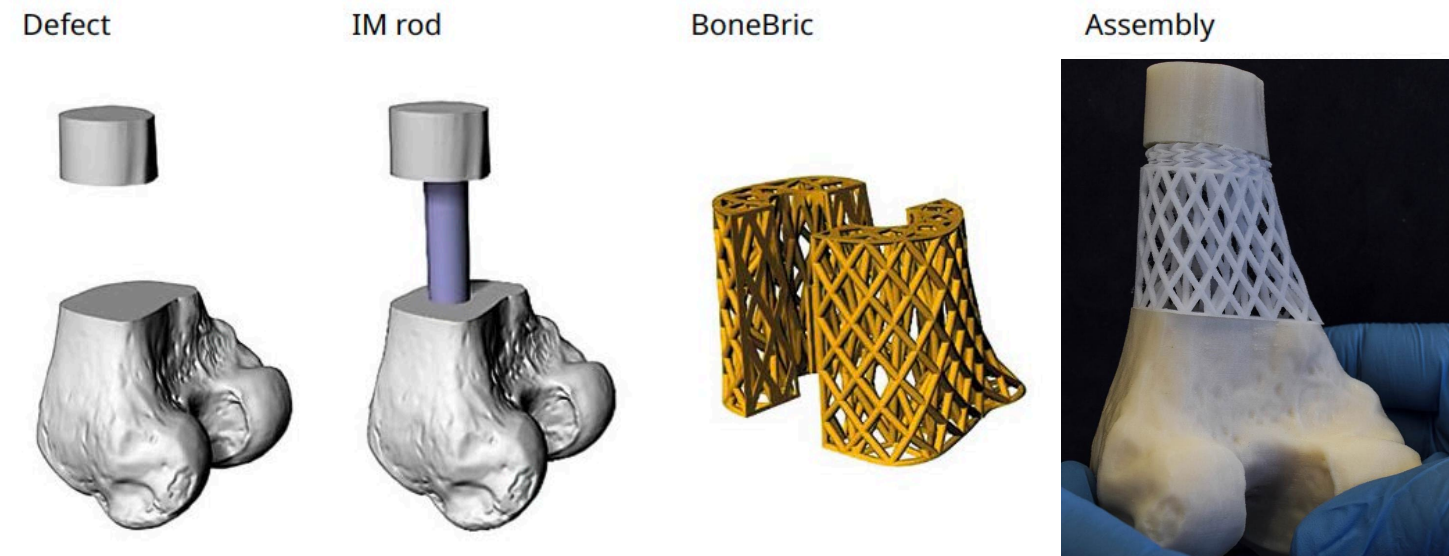
Custom-Made

Catalogue

Scaffold Guided Breast Augmentation

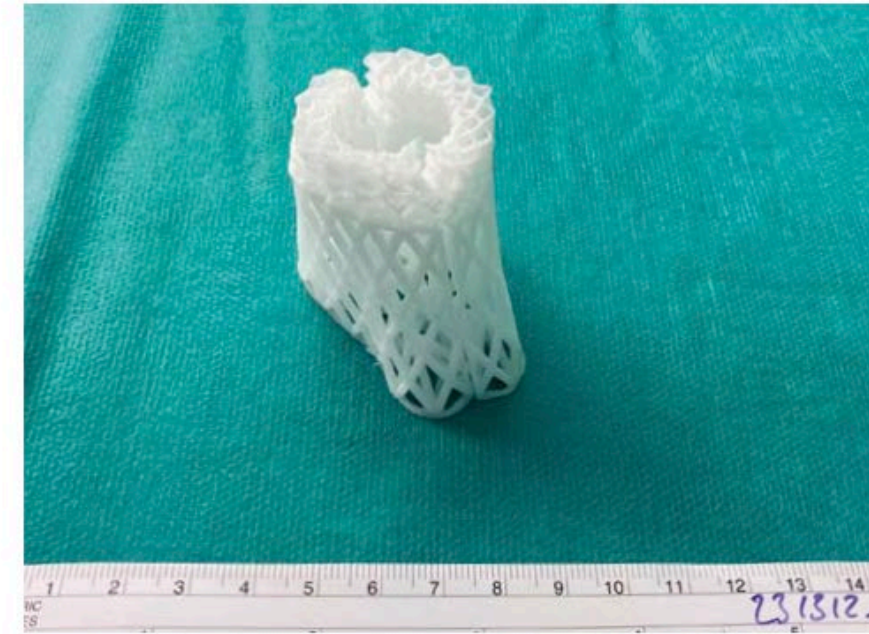


CMMD for Segmental Bone Defects

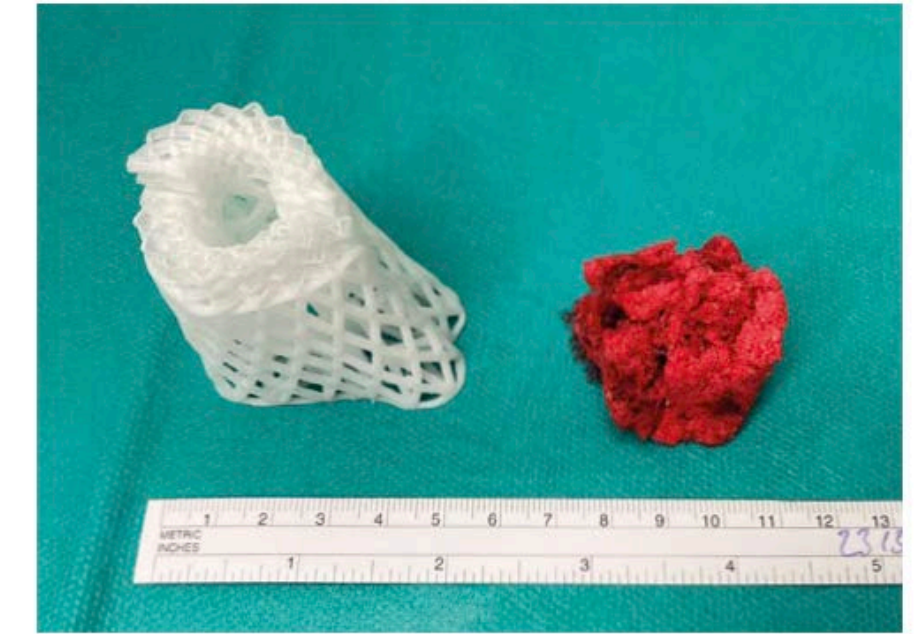


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BoneBric (assembled)



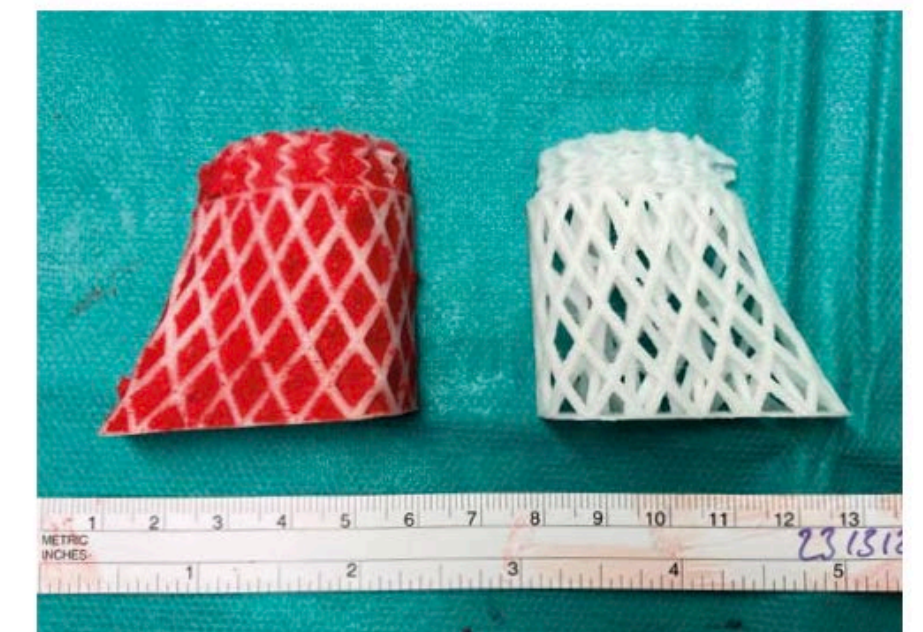
Assembled BoneBric (left) and reamed bone graft material (femur) (right)



BoneBric (separated)



Separated BoneBric with partially applied reamed bone graft material



Ongoing Clinical Trials in AUST



Two Trial sites in Brisbane, QLD (RBWH & PAH)

Clinical Indication	Number of patients operated	Longest Follow-up Period
Breast Implant Revision	9 / 120	11-months
Chest Wall Deformities (inverted breast scaffold)	5 / 20	34-months

- Scaffold insertion technique follows routine silicone implant insertion.
- The fat injection technique follows routine fat grafting methods.

Leipzig – Germany

- Management
- Design-Team
- Clinical Trial Team EU
- Manufacturing & Logistics
- Research & Development
- Customer Care

Brisbane – QLD, Australia

- Clinical Trial Team AUS
- Currently Two Clinical Trial Sites
- Expansion to 5+ sites in 2023
- Research & Development

2023/2024

- Design- and Manufacturing Hub Asia-Pacific / West Coast USA
- Customer Care – Global Coverage 24/7
- Implementation of a 3D-Think-Tank



Why QLD/AUST is the perfect country for our trials



1. Globally one of the highest reputation for medical registries – ensures Quality:

Global data compliance incl FDA, EMA, PMDA and Health Canada

2. High Speed implementation of clinical trials/regulatory

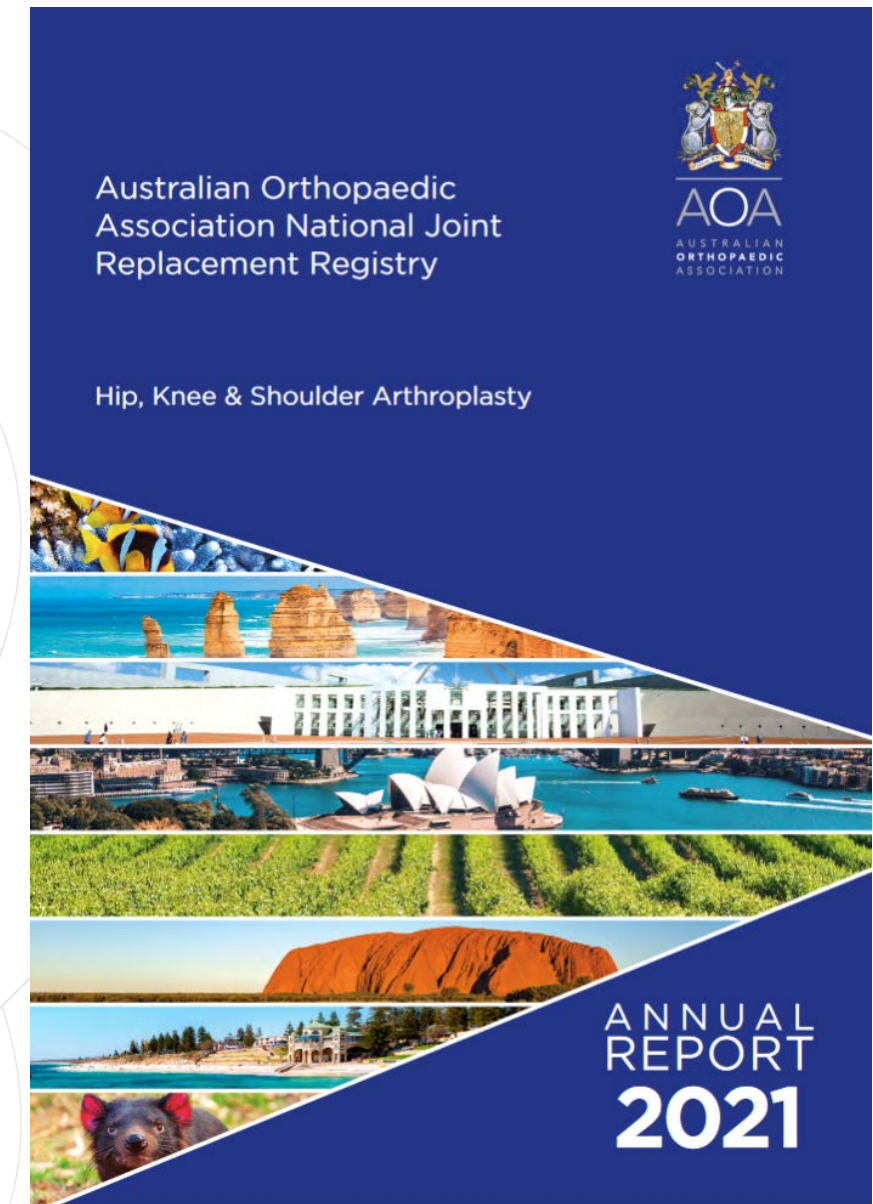
(Site Initiation Visit (SIV) to Study Start 4 – 6 weeks)

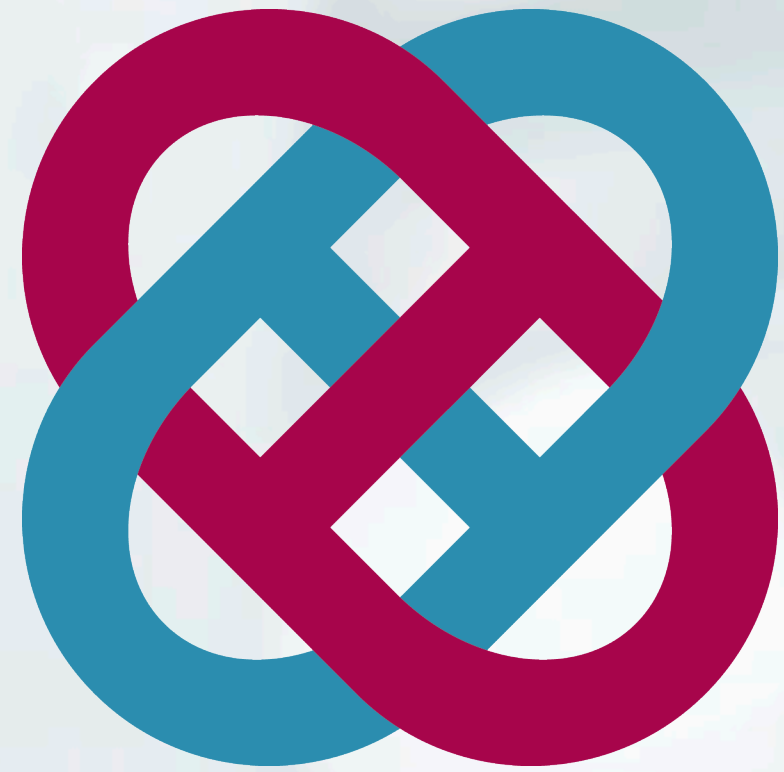
3. Cost: Australia/Queensland offers a highly attractive **R&D tax offset**

4. Major hospitals with **international known clinical experts (KOLs)** and world-class infrastructures

5. **Strong networks - Support from German Australian Chamber of Commerce & Trade and Investment Queensland** with introductions to local research partners, government agencies, contract manufacturing sites, clinical study and industry networks.

6. AUST Population very **open to new medical technologies** = seamless recruitment





Thank **You**