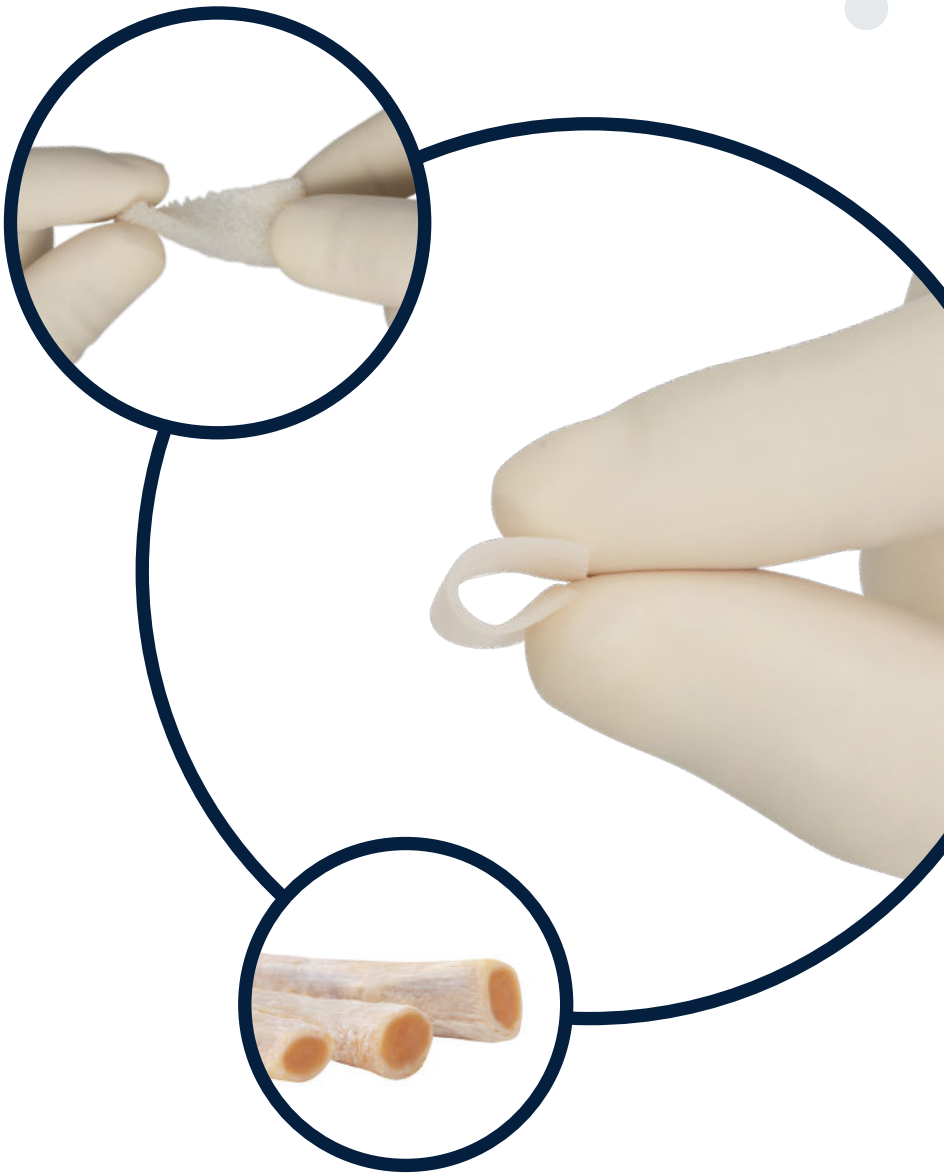
Plastic, ENT and Oral Maxillofacial

Allograft Product Portfolio



Australian Biotechnologies

Life Enhancing Allografts

Allograft Product Portfolio

About Us

Founded in 2000, Australian Biotechnologies honours the gift of donation through processing, manufacturing and distributing life enhancing allograft tissue products for the Australian community.

We supply over 45,000 allografts every year in Australia and our portfolio includes a wide range of advanced allograft products for use in orthopaedic, spinal, oral maxillofacial, plastic reconstruction and dental surgeries.

Our Facilities

We gained our Therapeutic Goods Administration (TGA) licence to process, store and distribute donated human bone and tissue in 2004. Since then, we have invested in the constant innovation and capability of our state-of-the-art cleanrooms and proprietary processes. We are governed and audited by the TGA and require compliance with the Australian Code of Good Manufacturing Practice, at all times. For this reason, our quality control process is multi-faceted and thorough to ensure that all allografts leaving our facility are to the highest safety and efficacy standards.

Our Patented Technology

To date we have completed approximately 30 Studies with the University of New South Wales. Through our research we have developed a new sterilisation and cleaning technology known as Super Critical Fluid (SCF CO_2), which has allowed us to offer allografts with advanced bone remodelling.

Since 2010 we have also developed the following:

- a demineralized bone matrix technology
- a freeze-dried allograft range that provides convenience of storage to hospitals and lowered delivery costs
- tendons and ligaments using SCF CO_2 technology
- machined and custom made allografts specific to patient needs for spinal and orthopaedic surgery
- a demineralized fibre technology which is 100% bone and is available in different configurations which provides excellent handling and inductive properties.

Allograft Availability

Australian Biotechnologies have further invested in a distribution network which has supplied over 600 hospitals nationwide, with specialty freezers containing various types of consignment allografts, available to any surgeon, at any time. This range includes orthopaedic and spinal allografts for various applications. In addition, Australian Biotechnologies have also provided dental and oral maxillofacial surgeons with a range that is specific to their applications. We have further invested in our clinical partnerships to provide much needed support to surgeons and their specific patient requirements.

All of the allografts listed in this portfolio are listed on the Prosthesis list and are 100% rebatable.

Education

We educate clinical nurse specialists each year, through a national education program. This includes an intensive 1-day program that not only explains the gift of donation but also the role of our Tissue Donation Partners and the processes the bone and tissue undergo to be viable, compliant allografts for implantation. The clinical nurse specialists receive a tour of our facility and are provided with the clinical requirements for safe handling and preparation of the allograft before and during the procedure. Our in-service team are currently taking this program to hospitals around the country, making it more accessible to all clinical nurse specialists, hospitals, and operating room staff.

Our Donation Partners

Australian Biotechnologies respects the wishes of tissue donors, by supporting our Tissue Donation Partners. They are Australian organisations who are responsible for retrieving the donated tissue from donors.

NSW GOVERNMENT Health
NSW Organ & Tissue Donation Service

Australian Tissue Donation Network®

Together with these Tissue Donation Partners, we have provided innovation, facilities, and capability to process, adapt, transform, and distribute allografts ready for implantation. This ensures donor wishes are honoured and a lasting gift is available to all fellow Australians. To date, over 200,000 Australians have received an allograft as a result of these partnerships.

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Traditional

Allovance® Osteoinductive grafts are only released after each batch is able to successfully demonstrate the osteoinductivity of the material using the 'gold standard' *in vivo* model through an independent, TGA licensed facility[1-4]. Allovance® Osteoinductive grafts are backed by real time stability studies demonstrating the osteoinductivity of the grafts is retained for the whole shelf life, as per TGA requirements[5-6].

The following products are manufactured with our Allovance® Osteoinductive processing technology.

Hybrid

Allovance® Hybrid

Product Name	Volume	Code	Product Description
Allovance® Hybrid	1cc	XP107	50% Mineralised Osteoconductive Cortical and Cancellous Granules (50:50 ratio) and 50% Demineralized Osteoinductive Fibres. Provided in 1cc syringe.
Allovance® Hybrid	2cc	CA151	50% Mineralised Osteoconductive Cortical and Cancellous Granules (50:50 ratio) and 50% Demineralized Osteoinductive Fibres. Provided in 2 x 1cc syringes.
Allovance® Hybrid	5cc	HY201	50% Mineralised Osteoconductive Cortical and Cancellous Granules (50:50 ratio) and 50% Demineralized Osteoinductive Fibres. Provided in 5cc syringe.

Product specifications:

This blend of Allovance® Osteoinductive Fibres with supercritical CO_2-treated bone granules forms a pure, biocompatible, and moldable bone graft material with enhanced surface nanotopography throughout, providing a cell-friendly environment for bony fusion.

Preservation method:

Freeze-Dried – store at room temperature

Key features:

- Osteoinductive bone fibres blended with osteoconductive granules
- Malleable and moldable, conforms to surgical site
- Resists irrigation
- Supplied pre-mixed and loaded into a delivery device
- 100% allograft bone, with no synthetic components or carriers added

Hybrid clinical applications:

- Gap between implant and peripheral bone (Jump Gap)
- Socket Preservation
- Sinus Augmentation
- Ridge Preservation techniques
- Major and Minor Ridge Augmentation
- Most grafting procedures

Product Name	Volume	Code	Product Description
Allovance® Hybrid Cortical Fibre Blend	2cc	XP106	70% Mineralised Osteoconductive Cortical Granules and 30% Demineralized Osteoinductive Fibres.

1. Urist MR. Bone: formation by autoinduction. Science 1965;150(3698):893–9.
2. Australian Code of Good Manufacturing Practice for human blood and blood components, human tissues and human cellular products, V1.0, April 2013
3. ASTM F2529-13 Standard Guide for in vivo Evaluation of Osteoinductive Potential
4. Katz JM, Nataraj C, Jaw R, Deigl E, Bursac P. Demineralized bone matrix as an osteoinductive biomaterial and in vitro predictors of its biological potential. J Biomed Mater Res B Appl Biomater 2009;89(1):127–34.
5. L. Shimp, "Heat resistance of allograft tissue," Cell Tissue Bank., vol. 9, no. 4, pp. 259–266, Dec. 2008.
6. Internal Report Data on file – (V1726)

Allovance®
Super Critical Fluid Technology
BONE ALLOGRAFT

Australian Biotechnologies utilises Super Critical Fluid Technology (SCF). This technology is the process of carbon dioxide being compressed while also being brought to a specific temperature so that it can exist in equilibrium as both a vapour and a liquid, this is what is known as SCF. Once in this state the SCF is able to diffuse through the bone matrix, to efficiently and effectively remove any unwanted immunogenic material. The temperature in which the fluid is brought up to does not exceed physiological temperature.

It is non-toxic and leaves no residual solvents.

The following products are manufactured with our Super Critical Fluid Processing Technology.

Crunch

Allovance® Crunch

Product Name	Particle Size	Volume	Code
Allovance® Crunch Fine	500µm - 1.0mm	2.5g	AB-SCFFG25

Produced from:
Osteoconductive cortical and cancellous bone

Preservation method:
Frozen

Key features:
- 100% allograft bone, with no synthetic components or carriers added
- Traditional osteoconductive particles which can be mixed with autograft or other bone graft materials
- Exposed nanotopography for rapid bone remodelling
- Non irradiated

Granules

Allovance® Granules

Product Name	Particle Size	Volume	Code
Allovance® Granules Fine	500µm - 1.0mm	5cc	AB-XP104
Allovance® Cortical Granules	500µm - 1.0mm	2cc	AB-CO103

Produced from:
Fine Granules - cancellous and cortical bone

Cortical Granules - cortical bone

Preservation method:
Freeze-Dried – store at room temperature

Preparation method:
Hydration

Key features:
- 100% allograft bone, with no synthetic components or carriers added
- Processed to expose the natural bone topography and provide optimal osteoconductive properties
- Preloaded in an Xpress delivery device for convenience

Crunch and Granules clinical applications:
- Can be mixed with autograft
- Sinus Augmentation
- Ridge Augmentation
- Implant Placement
- Periodontal Defects

Plate

Allovance® Plate

Product Name	Height	Width	Length	Code
Allovance® Plate	1mm	10mm	20mm	AB-CA170

Key features:

- 100% allograft bone, with no synthetic components or carriers added
- Cortical bone for space maintenance for bone graft particulates
- Natural bone matrix facilitates cell attachment and proliferation

Preservation method:

Freeze-Dried – store at room temperature

Plate clinical applications:

- Localised Ridge Augmentation
- Reconstruction of Alveolar Buccal Bone Plate
- Vertical and Horizontal Wall Defect
- Can be used in conjunction with Allovance® Hybrid to create a scaffold for guided bone regeneration
- Natural bone matrix facilitates cell attachment and proliferation
- Anterior Onlay Augmentation
- Reconstruction of Anterior Alveolar using Khoury Technique

Cortical Flex

Allovance® Cortical Flex

Product Name	Height	Width	Length	Code
Allovance® Cortical Flex	1mm	20mm	40mm	AB-MB204

Key features:

- 100% allograft bone, with no synthetic components or carriers added
- Thin plate of demineralized cortical bone for space maintenance for bone graft particulates
- Can be easily cut into shape with scissors, once hydrated

Preservation method:

Freeze-Dried – store at room temperature

Cortical Flex clinical applications:

- Vertical and Horizontal Wall Defect
- Localised Ridge Augmentation
- Onlay Bone Graft
- Used as a laminar plate bone membrane (not a collagen membrane substitute)
- Can be used in conjunction with Allovance® Hybrid to create a scaffold for guided bone regeneration

Cancellous Flex

Allovance® Cancellous Flex

Product Name	Height	Width	Length	Code
Allovance® Cancellous Flex	5mm	20mm	40mm	AB-MB202

Key features:

- 100% allograft bone, with no synthetic components or carriers added
- Thin demineralized “sponge like” cancellous bone for space maintenance for bone graft particulates
- Can be easily cut into shape with scissors, once hydrated

Preservation method:

Freeze-Dried – store at room temperature

Cancellous Flex clinical applications:

- Genioplasty
- Maxillary repositioning osteotomies
- Used in Orthognathic procedures

Unicortical Block

Allovance® Unicortical Block

Product Name	Width	Minimum Cortical Thickness	Code
Allovance® Unicortical Block	15mm	2mm	AB-CA172

Key features:

- 100% allograft bone, with no synthetic components or carriers added
- Cortical and cancellous surface - can be shaped as needed prior to implantation
- Retains osteoconductive properties due to preservation of natural bone matrix

Preservation method:

Freeze-Dried – store at room temperature

Unicortical Block clinical applications:

- Orthognathic block for LeFort I Osteotomies
- Can be used in conjunction with custom plates
- Orthognatic Surgery
- Localised Ridge Augmentation using a Block Allograft with subsequent implant placement
- Ridge Augmentation prior to implant placement.
- Craniofacial Reconstruction
- Ridge Volume Deficiencies
- Can be used in conjunction with Allovance® Hybrid to create a scaffold for guided bone regeneration

Allovance®
Super Critical Fluid Technology
SOFT TISSUE ALLOGRAFT

Super Critical Fluid Technology (SCF) is a state-of-the-art technology that uses carbon dioxide in a Super Critical State. This state is achieved by applying precise temperature, which does not exceed physiological temperature, and pressure to the carbon dioxide, which allows it to exist in a unique state as both a liquid and a gas. Carbon dioxide in this Super Critical State is then able to diffuse through the soft tissue, efficiently and effectively removing any unwanted immunogenic material.

The application of this technology can be used in the processing of soft tissue allografts as terminal bioburden reduction. Terminal processing can be achieved while maintaining the intrinsic mechanical properties of the graft. As a solvent for removing lipids and immunogenic materials, the SCF fluid can reach pathogens within the soft tissue.

The SCF fluid is non-toxic and leaves no solvent residue.

The following products have been processed with our Super Critical Fluid Processing Technology.

Fascia Lata

Allovance® Fascia Lata

Product Name	Size	Code
Allovance® Fascia Lata	40mm x 40mm	AB-FL101
Allovance® Fascia Lata	20mm x 100mm	AB-FL102

Key features:

- 100% allograft bone, with no synthetic components or carriers added
- Natural connective tissue allograft sourced from the lateral thigh

Preservation method:

Frozen

Fascia Lata clinical applications:

- Used to restore and repair soft tissue, including facial reconstruction and animation procedures
- Interpositional grafting (temporomandibular joint surgery)
- Treatment of musculoskeletal trauma (lower eyelid surgery)
- Soft tissue repair (augmentation of nasal dorsum, cleft lip/palate)
- Dorsal Onlay Graft
- Orbital Socket repair

Acellular Dermal Matrix

Allovance® Acellular Dermal Matrix

ADM – Thin

Thickness range:
0.7mm – 1.2mm

Product Name	Height	Width	Code
20x40mm - THIN	20mm	40mm	AB-ADM-2040-TN

Key Features:

- Non-irradiated
- No harmful chemical preservatives used to store the tissue

Traditional

The Traditional allografts are minimally processed and utilised to restore musculoskeletal tissue. Comprised of 100% human tissue, the graft integrates with the patient's own tissue during the healing process.

Costal Cartilage Segment

Product Name	Length	Width	Code
Costal Cartilage Segment	>30mm	>8mm	AB-CC102
Costal Cartilage Segment	>40mm	>8mm	AB-CC104

Key features:

- Pre-cut costal cartilage segment
- Strong, flexible and can be shaped to fit the specific needs of the patient

Preservation method:
Frozen

Costal Cartilage Segment clinical applications:

- Septorhinoplasty
- Rhinoplasty
- Ear Reconstruction
- Tracheal Reconstruction
- Craniomaxillofacial Reconstruction
- Laryngotracheal Reconstruction

Costal Cartilage Strips

Product Name	Length	Width	Code
Cartilage Strip Small - Single	25-29mm	>8mm	AB-CS101
Cartilage Strip Medium - Single	30-39mm	>8mm	AB-CS102

Definitions

Demineralized Bone Matrix

Demineralized bone matrix (DBM™) is a type of bone graft material derived from processed allograft bone. It is created by removing the mineral content from the bone, leaving behind the organic collagen matrix. This process enhances the graft's osteoinductive properties, meaning it can stimulate new bone formation when used in bone repair or regeneration procedures. DBM™ is commonly used in orthopaedic surgeries, dental implants, and other procedures requiring bone grafting. It is valued for its ability to promote bone healing and integration with the surrounding bone tissue.

Mineralised Bone Allografts

Mineralised bone allografts have been minimally processed as to maintain both the organic (collagen) and inorganic (mineral) matrices of the tissue. The mineral content gives the bone its hardness and strength, allowing it to support and protect the body's structures. Mineralised bone allografts provide an osteoconductive scaffold for cell attachment. It is commonly used in bone grafting procedures to promote bone healing and regeneration, leveraging its natural structure and composition to integrate with the patient's own bone.

Super Critical Fluid Technology (SCF)

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It is non-toxic and leaves no residual solvents.

Australian Biotechnologies

Life Enhancing Allografts

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