Tissue Products Catalogue

emcm
European Medical Contract Manufacturing

Supporting Opportunities

eCOO® Technology

EMCM

Established in 1993 with 5 employees, EMCM today is a biomedical company with more than 1500 m² clean room area and over 75 employees. It has developed into a centre of excellence in developing and manufacturing sterile medicinal products in GMP and ISO accredited facilities that cater to the markets of Biomaterials, Pharmaceuticals and Tissue Engineering specialties conforming to the standards of the USFDA, EMEA & ANVISA.

GMP

ISO

FDA

Tissue Processing: eCOO® Technology

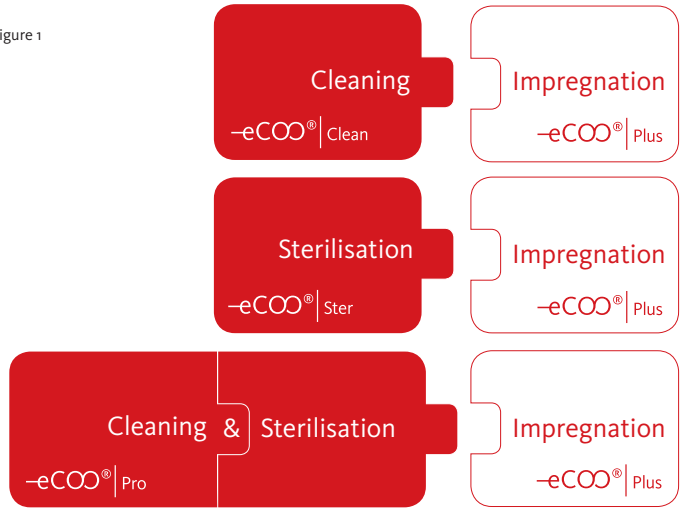
Our Tissues business segment is focused on processing tissue components such as bones, soft tissues and skin of both human and animal origin. Our core competency is providing safe, clean and innovative products using our proprietary supercritical carbon dioxide ($scCO_2$) technology: eCOO® Technology.

Carbon dioxide is in its supercritical state when both the temperature and pressure equal or exceed the critical point of 31°C and 73 atm. In this supercritical state, CO_2 has both gas-like and liquid-like qualities providing the ideal conditions for cleaning and sterilising a wide variety of tissues. $scCO_2$ can effuse through tissues like a gas and dissolve materials like a liquid. By controlling or regulating pressure and temperature, the density or solvent strength of $scCO_2$ can be tuned to simulate a wide range of organic solvents. This dissolving power is applied to purify and sterilise a wide variety of tissues [1]. EMCM's $scCO_2$-based technology furthermore meets the international sterilisation standard SAL 6. After the terminal sterilisation procedure, the tissue products can either be stored fresh-frozen or freeze-dried after which the product can be stored at room temperature.

The incorporation of steps, using $scCO_2$, is brand named eCOO® Technology. The eCOO® Technology brand encompasses several technology handles for cleaning, sterilising and impregnating; both biological and synthetic grafts. The decellularisation and defatting procedure is called eCOO® Clean. The sterilisation process is called eCOO® Ster. The process including both cleaning (decellularisation & delipidisation) and sterilisation is called eCOO® Pro. Impregnation of tissue grafts may be based on our eCOO® Plus procedure which can be added to the other eCOO® modules independently.

Figure 1 illustrates the various options of eCOO® Technology.

Figure 1



The eCOO® advantage

Current cleaning and sterilisation methods often use harsh chemical treatments which can affect the inherent mechanical and structural properties of the tissue grafts [2]. Several studies have shown that these methods can have detrimental effects on protein structure, adsorption rate, cell adhesion and tensile strength [3] [4] [5]. In addition, these methods are often lengthy processes and require elaborate rinsing steps.

In contrast, cleaning tissue with EMCM's eCOO® Clean technology and subsequent eCOO® Ster sterilisation minimally affects the structural integrity of the tissue grafts yet can still reach SAL 6 sterility levels and viral inactivation. Biomolecular properties (e.g. protein degradation and cell adhesion) and mechanical properties (i.e. tensile strength and maximum torque) are retained making eCOO® Technology-based tissue processing/ sterilisation ideally suited for indications requiring tissue grafts that support weight-bearing and/or tension-sensitive applications. Furthermore, the system is highly customisable to meet the tissue specific requirements and leaves minimal carbon footprint.

The eCOO® advantage:

- Retainment of structural and mechanical properties
- Exceeds SAL 6 sterilisation standard
- Viral inactivation
- Minimal residues of harsh and hazardous material
- Customisable
- Environmentally friendly

[1] A. Nichols, D. C. Burns en R. Christopher, *'Studies on the Sterilization of Human Bone and Tendon Muscoskeletal Allograft Tissue Using Supercritical Carbon Dioxide'*, Journal of Orthopaedics, 2009

[2] N. A. Russel, A. Rives, M. H. Pelletier, W. J. Bruce en W. R. Walsh, *'The effect of sterilization on the mechanical properties of intact rabbit humeri in three-point bending , four-point bending and torsion',* Cell Tissue Bank, 2012

[3] Russell, N. et al., *The effect of sterilization methods on the osteoconductivity of allograft bone in a critical-sized bilateral tibial defect model in rabbits*, Biomaterials, 2013

[4] Nguyen, H. et al., *Reducing the radiation sterilization dose improves mechanical and biological quality while retaining sterility assurance levels of bone allografts*, Bone, 2013

[5] Almeida, OM., et al., *Comparative study and histomorphometric analysis of bone allografts lyophilized and sterilized by autoclaving, gamma irradiation and ethylene oxide in rats*, Acta Cir Bras, 2013

Tissue products

Based on its proprietary eCOO® Technology, EMCM offers a wide variety of tissue products.

eTiss® allografts

Allografts are derived from human donor material. For all donors a full medical history is required. Medical records are verified, a physical examination is performed and next of kin and/or general practitioners are consulted, to assure that there are no contra-indications for donation. The tissue is recovered under aseptic conditions and tested for HIV, hepatitis B and C, HTLV and syphilis, utilising qualified testing laboratories. Tissue donation takes place under stringent quality and safety regulation and all procedures are subjected to European legislation and guidelines concerning human tissue and fulfil the requirements of the respective association of tissue banks and the relevant authorities.

eColl® xenografts

Xenografts are derived from animal-based material such as bovine and porcine material. These materials are obtained from closely monitored herds from BSE-free countries and subjected to stringent testing for transmissible diseases.

Once cleared, the tissue products are cleaned and sterilised using our proprietary eCOO® Technology.

Applications

EMCM's eTiss® and eColl® products have a wide range of applications varying from orthopaedic indications, traumatology, sports medicine, cardiovascular and spinal and dental surgery.

The eTiss® and eColl® advantage:

- Clean and sterile (SAL 6) high-end tissue products without compromising on the structural integrity
- Excellent biocompatibility & improved regenerative properties
- Customisable to meet tissue-specific demands
- Minimal residues of harsh and hazardous material

eTiss®

The products developed at EMCM under the eTiss® family are classified as Human Tissue, as per the EU directives, and are available for distribution in most European countries. Depending on the use of the allograft, different forms and shapes can be manufactured.
Also the volume of deliverance can be customised to your request.
eTiss® products can be enriched by impregnating them with infection controlling agents such as antibiotics and bioactive agents (i.e. growth factors). This impregnation may be based on our eCOO® Plus procedure.

Process

- eCOO® Clean
- eCOO® Ster
- eCOO® Pro
- eCOO® Plus

Applications

- General orthopaedics
- Spinal surgery
- Trauma
- Periodontology
- Sports injuries

Features

- Lower risk of transmitting disease than currently available products
- Excellent osteoconductive and osteoinductive (DBM) properties
- Mechanical and structural properties of tissue are minimally affected
- SAL 6 sterility
- Impregnatable with infection controlling and bioactive agents
- Broad range of clinical applications possible

1 Void fillers

Cancellous bone, processed with the eCOO® Technology has excellent osteoconductive capacity and forms a stable complex with the adjacent bone of the patient. The variety in shape and form of the cancellous bone can match the different sizes of the bone defect. For dental applications, special blocks and extra fine chips are available. Void fillers can be used for a wide variety of **general orthopaedic** and **dental applications**.

Article number	Description	Volume
297119	Cancellous chips; 1,5 – 10 mm	5 – 90 cc
297124	Cancellous/cortical chips (50%/50%); 1,5 – 10 mm	30 – 90 cc
297127	Cortical/Cancellous granules (80%/20%); 0,5 – 5 mm	5 – 90 cc

2 Structural grafts

Bone tissue is one of the most frequently used tissue for transplantation in the field of **orthopaedic**, **plastic**, **maxillofacial** and **neurosurgery**. Pre-cut bone allografts are used to restore boneless weight baring positions due to trauma, tumour removal, and osteoporosis or to correct bone deformities. These bone allografts are cleaned and sterilised with EMCM's eCOO® Technology. Various structural grafts are available in multiple dimensions. Structural grafts can be used in a wide variety of applications, such as **lumbar fusion**, **cervical spinal fusion** and **fracture management**.

Article number	Description	Size
297132	Iliac crest wedges	6 – 10 mm
297147	Femoral shafts	30 – 200 mm
297161	Tibial shafts	40 – 150 mm
297137	Cervical spacers	5 – 12 mm
297173	Femoral cortical struts	100, 150, 200 mm
297210	Femur grafts (L/R)	Whole femur
297212	Tibia grafts (L/R)	Whole tibia
297214	Humerus grafts (L/R)	Whole humerus

3 Femoral heads

Femoral heads are obtained from donors undergoing hip replacement surgery. The femoral heads are fully cleaned and sterilised after which the surgeon can model the bone to the optimal shape to meet the patients' requirements. Femoral heads can be used in **hip-replacement surgery** and **general orthopaedic reconstruction**.

Article number	Description	Size
297105	Full femoral head	≥ 44 mm
297192	Half femoral head	

4 Demineralised Bone Matrix

Demineralised Bone Matrix (DBM) is derived from cortical bone which is processed with eCOO® Technology and subsequently demineralised to expose matrix encapsulated growth factors, such as bone morphogenetic proteins (BMPs). These growth factors have been shown to induce osteoinduction improving the bone regeneration process significantly. DBM is available in powder, gel & putty and can be delivered as ready-to-use syringe. DBM can be used in a wide range of indications such as **trauma**, **periodontology** and **spinal surgery**.

Article number	Description	Volume
297206	DBM powder	0,5 – 10 cc
297198	DBM gel	0,5 – 10 cc
297202	DBM putty	0,5 – 10 cc

5 Soft tissues

Tendon allografts play an important role in tendon and ligament reconstruction, particularly where there is a shortage of suitable autologous tissue. Tendon tissue allografts such as achilles and patellar ligaments are frequently used in **sports related injuries**.

Article number	Description	Size
297216	Anterior tibialis tendon	20 – 40 cm
297217	Posterior tibialis tendon	21 – 40 cm
297218	Gracilis tendon	20 – 40 cm
297219	Patella bone-tendon-bone	8 – 20 cm
297220	Achillis tendon	20 – 40 cm

eColl®

Collagen is increasingly used for repair and reconstruction in the field of **maxillofacial reconstruction**, **urology**, **wound management**, **cosmetic and plastic surgery**. The eColl® products are derived from dermal, pericardial or tendon animal tissue and cleaned by EMCM's eCOO® Clean technology to remove lipids and cellular components. eColl® products are available as membranes, fleeces and scaffolds in various dimensions.

eColl® products can be enriched by impregnating them with infection controlling agents such as antibiotics and bioactive agents (i.e. growth factors). This impregnation may be based on our eCOO® Plus procedure.

Process

- eCOO® Clean
- eCOO® Ster
- eCOO® Pro
- eCOO® Plus

Application

- Implantology
- Spinal surgery
- Periodontology
- Cardiovascular
- Urogenital
- Oral surgery

Features

- Highly biocompatible
- Biomechanical and structural properties are retained
- Multidimensional structures allow broad range of clinical applications
- SAL 6 sterility
- Broad range of clinical applications possible
- Impregnatable with infection controlling and bioactive agents

1 eColl® membrane and eColl® dermis

This pericardium membrane for soft tissue augmentation provides a long-lasting, adequate barrier function. Due to the production process, the properties of the native pericardium membrane are preserved and have the characteristics of natural tissue. The eColl® membrane can be applied for a wide range of indications such as **periodontology**, **neurology** and **otolaryngology**. The eColl® dermis, obtained from either porcine or bovine origin can be used for various indications where membrane reconstruction and mechanical strength are required such as **hernia's**, **breast reconstruction** and **multiple gingival recession**.

Description	Size
Porcine collagen membranes	Various
Bovine collagen membranes	Various

2 eColl® fleece

The wet-stable collagen fleece can be used for accelerated wound healing and haemostatic application. It contains native resorbable collagen fibrils which can be populated by fibroblasts to facilitate tissue repair. The surface of the fleece provides an ideal basis for the adhesion of platelets and the reinforcement of the forming coagulum. Applications range from **hemostat applications** during surgery to the treatment of **superficial burns** and **chronic disease-associated ulcers** such as **diabetic foot ulcers**.

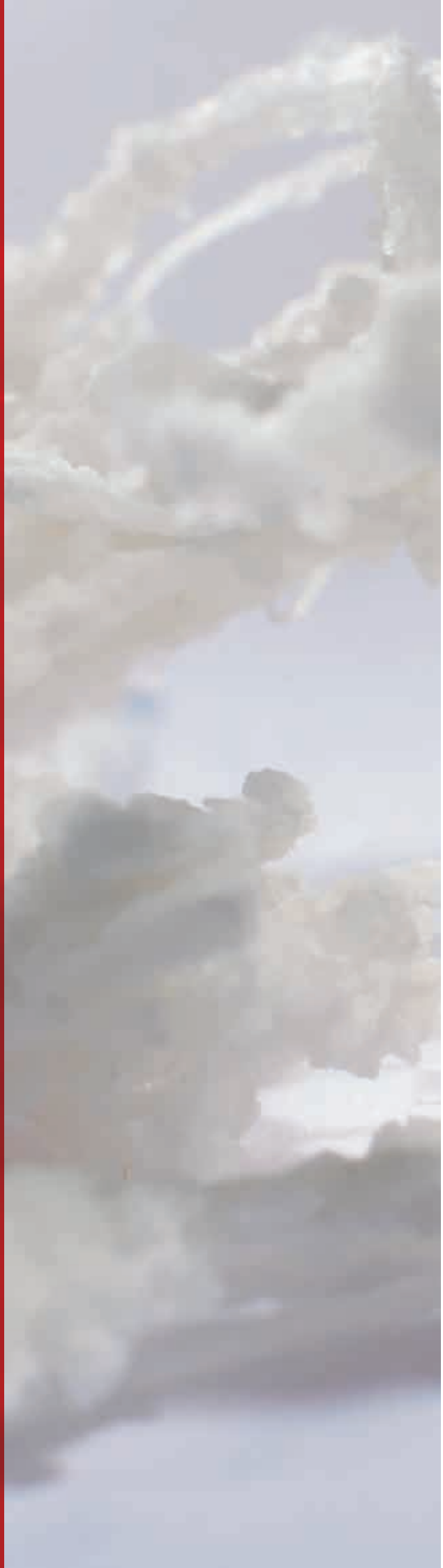
Description	Size
Porcine collagen fleece	Various
Bovine collagen membranes	Various

3 eColl® scaffolds

Collagen scaffolds can be used for a wide variety of tissue engineering applications where tissue reconstitution is desired. A wide variety of scaffolds will be available in the near future ranging in size, diameter and thickness. Applications: **urological tissue reconstruction**, **cardiovascular surgery** and **gastroenterology**.

Description	Size
Tubular constructs	6 – 15 mm diameter

More eColl® products are in development



eNova®

EMCM is actively pursuing the development of innovative biomaterials by combining our in-house expertise on allografts and collagen molecules with synthetics. This has resulted in the development of novel tissue products with controlled release of active pharmaceutical ingredients (APIs) such as antibiotics. Both eTiss® and eColl® products with sustained and controlled release of APIs and bioactive peptides are currently being developed. The eNova® product portfolio will be subject to significant expansion with innovative biomedical products serving a wide range of applications

Process

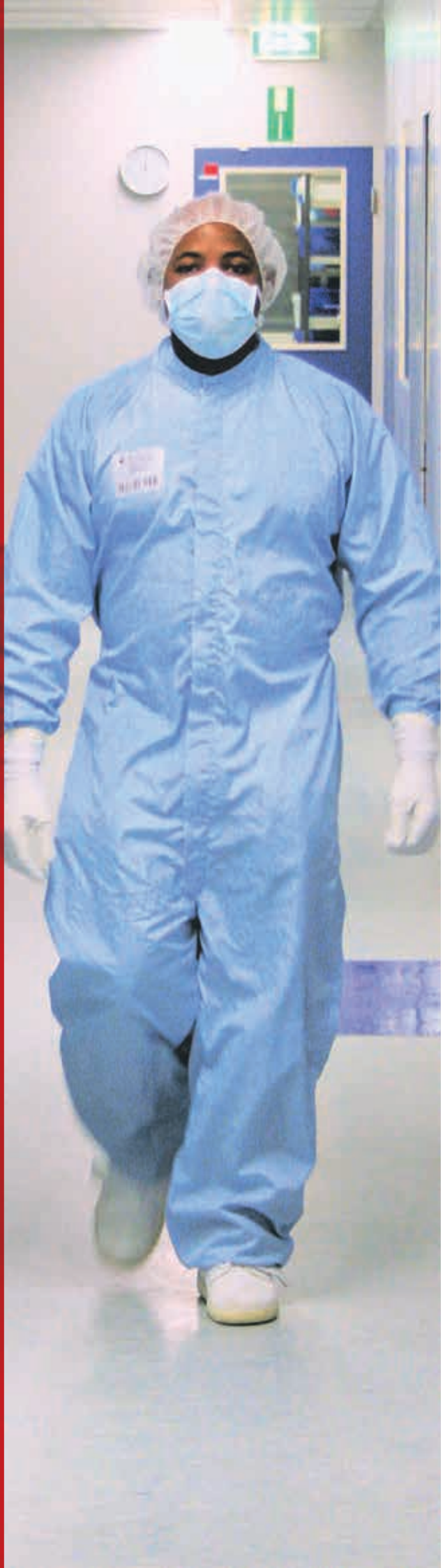
- eCOO® Technology

Applications

- Implantology
- Periodontology
- Oral surgery
- Orthopaedic surgery
- Trauma surgery
- Spinal surgery

Features

- Controlled drug/peptide release based on eCOO® Technology



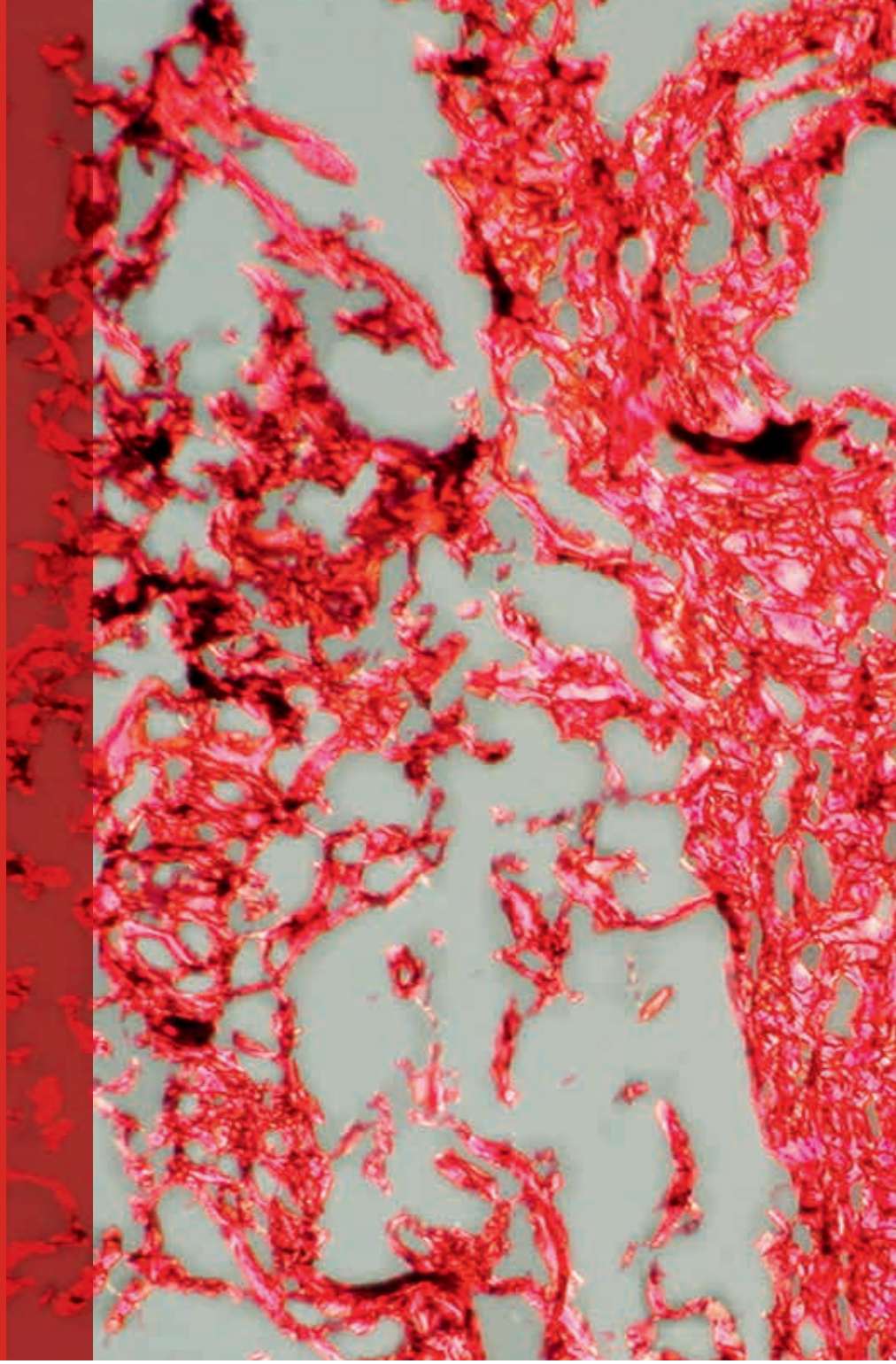
Quality

EMCM is a GMP licenced institution, processing a broad range of healthcare products for the pharmaceutical, medical devices and tissue engineering segment in the healthcare industry. In credence to its quality compliance, EMCM has been successfully inspected by the USFDA, ANVISA and other European authorities for providing products to the global markets. EMCM is a member of the European Association of Tissue Banks (EATB).

EMCM has been granted a licence according to the European Directive 2004/23 as a Tissue Establishment by the Ministry of Health in The Netherlands. Human tissue products processed at EMCM are sterile and fulfil the quality & safety requirements of the European directives for tissue and cells. EMCM complies to the norms required by the VWA Netherlands to import and handle animal by-products. EMCM is your partner, supporting you with innovations in human grafts (eTiss®), xenografts (eColl®) and innovative biomaterials (eNova®).

All human tissue donors are serologically tested for blood and tissue transmissible infectious diseases. These tests are performed and released by a certified laboratory. Human tissue processed at EMCM is derived from donors who fulfil all the requirements of the European Directives for quality and safety of human tissue and cells (2004/23EU 2006/86EU and 2006/17EU) which include negative test results covering Hepatitis B/C, Syfilis, HIV, amongst others. We would be happy to share with you our serology criteria upon request.

The production of human and animal based products is clearly separated within the complex & business and is in full compliance with the European and International regulatory guidelines.



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