

Marburg Bonebank-System

For thermal disinfection
of femoral head allografts
from living donors



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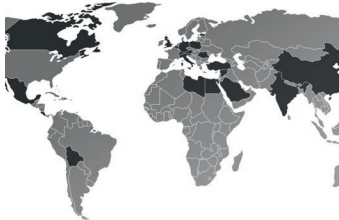
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Innovative medical technology since 1975



Ever since it was founded in 1975, telos has been involved in the development of innovative medico-technical solutions for orthopedic and traumatologic applications.



Today, telos products are distributed worldwide through sole agencies in 22 countries.

The Marburg Bonebank-System

With the introduction of modern deep-freezing techniques, allogenic bone transplantation has become a well-established therapeutic concept in orthopedic and traumatologic surgery.



The Marburg Bonebank - System for thermal disinfection of femoral head allografts from living donors was developed in 1993. Today, more than 900 systems are in use worldwide.

The compact system consists of an electronic control system, the so-called Lobator, and a sterile disinfection set, providing for virus inactivation of HIV 1, HIV 1/0, HIV 2, HTLV, CMV, hepatitis B and C as well as for inactivation of syphilis and vegetative infectious agents, while preserving the biomechanical and biological valence of the allograft.

Features of the Marburg Bonebank - System:

- Thermally disinfected femoral head allografts are approved medicinal products (PEI.H.03410.01.1)
- No quarantine storage required
- No second donor testing required
- Easy acquisition of femoral head allografts, which are resected as redundant tissue during primary hip arthroplasty procedures
- Allograft production, processing and storage on site in clinic bone banks
- Safe and cost-saving allografts

... no reported adverse events or reactions to date with more than 200,000 patient!

LOBATOR Control Unit

Marburg Bonebank-System

The LOBATOR electronic control unit is the essential device for thermal disinfection of femoral head allografts from living donors.



LOBATOR sd-1 (1993)

Electronic control unit with temperature control for the heating unit and separate cooling plate.



LOBATOR sd-2 (1996)

Micro controlled heating and cooling of the heating unit with documentation of all process steps.



LOBATOR sd-3 (on request)

Computer control unit with touch screen for controlled heating and cooling of the heating unit; dual documentation of each process step; web-enabled for remote maintenance and storage of all process data on a central server; memory capacity geared to statutory documentation requirements.

Fields of application:

- Joint replacement surgery
- Spine surgery
- Tumor surgery
- Post-traumatic reconstructive surgery

Indications for use:

- Revision arthroplasty
- Correction of deformities
- Multi-fragment and comminuted fractures
- Bone loss from infection
- Pseudarthrosis
- Spinal fusion

Performance:

- For femoral heads up to 56 mm in diameter
- Inactivates HIV 1, HIV 1/0, HIV 2, HTLV, MV, CPV (model virus for HPV B19/hepatitis B), BVDV (model virus for hepatitis C) viruses
- Inactivates syphilis
- Inactivates infectious vegetative bacteria
- Reduces the graft's fat content
- Broadly preserves the bio-mechanical and biological valence of the graft
- Eliminates the recontamination risk, using a closed system
- Takes 94 minutes for the process (minimum temperature of 82.5 °C within the center of the femoral head for at least 15 minutes)
- Permits easy intra-operative use



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The disinfection-set complies with the high quality and safety standards of the EC Tissue Directive 2004/3/EC of 31-03-2004, the 2006/1/EC Commission Directive of 08-02-2006 and the 2006/86/EC Commission Directive of 24-10-2006, transposed into German law through the TPG regulation for transplantations (TPG-GewV) of 26-03-2008 and with the German AMWHV regulation of 04-04-2008, governing the manufacture of medicinal products and agents.

Accessories

Marburg Bonebank-System



DISINFECTION-SET

The two-part external packaging is made of polystyrene, with a thread mechanism and an Evoprene seal providing for sterile closure.

The disinfection container is made of Makrolon and consists of two chambers, thus complying with the requirements placed on clean room class A in B.

The bottom part of the container accommodates the femoral head and is filled with the disinfection medium up to the marking line. The lid, also called transfer container, is used for sterile closure of the bottom chamber and for taking up the disinfection liquid at the end of the process.

The disinfection set consists of an external packaging and a disinfection container.



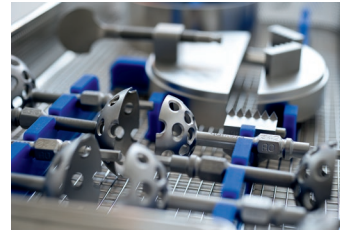
TRANSPORT- AND STORAGE CONTAINER-SET

The transport- and storage container-set is equipped with a double hard packaging for contamination-free tissue storage.

It is supplied sterile and can be stored at temperatures down to minus 80° Celsius.

The inner container consists of Makrolon, the outer of polystyrene.

For container closure, safety threads are provided in 3 colors (traffic light system).



SPIERINGS FEMORAL HEAD REAMER-SET

Cartilage and cortex are removed from the resected femoral head using the cartilage reamer set.

Inverted Reamers are available in nine sizes. Furthermore, the set comprises a femoral head fixation facility and a splash shield.



DOCUMENTATION-SET

The documentation-set includes both, donor and recipient documents, among others the following:

- Living donor informed consent
- Medical history and examination results of the donor
- Donor serological and microbiological testing
- Allograft release through authorized person as per §20 c of the German Medicinal Products Act (AMG)

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