International allocation

A transfer of transplants to international locations is possible if the import is approved and all necessary documents are available. The tissue allocation office and the quality management of the DGFG will help with the clarification and implementation.
The delivery time for orders outside Germany is dependent on the distance and country-specific requirements. The DGFG makes every effort to keep waiting times as short as possible. For increased flexibility, it is possible to store several AC+ on site in a suitable freezer (< -60°C). The DGFG charges an expense allowance for the provision of the transplants and the transport costs for the delivery.

Patient registration

After clarification and preparation of all necessary regulations the registration of a patient is carried out by transmitting the relevant data via the internet-based recipient database *www.gewebetransplantation.de*, by fax or e-mail, in urgent exceptional cases also by telephone.

Ordering options and delivery

www.gewebetransplantation.de
Recipient database with online account

49 (0) 511/563559-5200

vs@gewebenetzwerk.de

+49 (0)511/563559-30 /-54

The German Society for Tissue Transplantation (DGFG)

Since 1997, the DGFG has organised tissue donation in a nationwide network and provides patients with tissue transplants. The DGFG is a non-profit organisation. Shareholders are the Hannover Medical School, the University Hospitals of Dresden, Leipzig, Rostock and the Dietrich Bonhoeffer Clinic in Neubrandenburg. In accordance with the statutes, all surpluses achieved are used exclusively to promote tissue medicine. The network thus complies with the provisions of the German transplant law, which expressly prohibits trade in and profit from tissues.

The DGFG supports the cooperation partners in tissue donation, tissue processing and tissue allocation. The DGFG provides corneas, amniotic membranes, heart valves, blood vessels, musculo-skeletal tissues and special preparations like LaMEK and the AC+. All transplanting institutions within Germany can obtain tissue transplants from the DGFG. Foreign institutions can obtain tissue transplants if these are available in sufficient quantities.

Your contact persons

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AmnioClip-plus cryopreserved

PEI.G.11968.01.1

Application

The AmnioClip-plus (AC+) is used in ophthalmology to treat eye surface disorders, to preserve the eye, maintain or improve vision and is useful for therapy of dry eye syndrome.
AC+ can be applied in most situations where the use of amniotic membrane is common practice today, e.g.

- Persistent epithelial defects including neurotrophic corneal ulcers (on host cornea/corneal transplants)
- Reconstruction of conjunctival injuries (e.g. burns or chemical burns, perforating trauma)
- Pterygium surgeries
- Symptomatic bullous keratopathy
- High-risk keratoplasty for limbal stem cell deficiency

Amniotic transplant safety

In Germany, tissue preparations are subject to the German Medicinal Products Act, where extensive approval and safety regulations apply. The German Society for Tissue Transplantation (DGFG) is approved for tissue preparation and transplantation in accordance with § 20 b and § 20 c of the German Medicinal Products Act. Each tissue donation is fully documented and traceable from consent to processing and transplantation.

About the Amnion

The amniotic membrane (AM) is the tissue surrounding the foetus in utero consisting of epithelium and stroma. AM can be easily extracted and preserved. Immunotolerance, promotion of epithelialisation, anti-inflammatory, anti-angiogenic, anti-fibroblastic and antimicrobial properties conferred characteristics of AM.
The snap freezing of fresh samples during the production of AC+ preserves the desirable characteristics of the AM as compared to freeze dried sample collection methods.
The AM is obtained from donors during planned Caesarean section. Consent is obtained from each donor after comprehensive donor evaluation and infection diagnostic analysis has been completed. The donated AM is prepared under clean room conditions conditions and subjected to extensive quality controls, including microbiological examinations.

AmnioClip-plus advantages compared to conventional amniotic membrane transplantation (AMT)

AmnioClip-plus, in contrast to conventional AMT, eliminates the requirement for suture-associated procedures therefore avoiding surgical trauma. The treatment is repeatable and suitable for therapy of protracted/chronic defects.

- Easy to use
- Outpatient treatment
- Only local anaesthesia necessary
- Minimal invasive method
- Minimal irritation
- Repeated treatment possible

Literature/Sources
Engelmann K, Kotomin I, Knipper A, Werner C. Nahtlose Amnionmembrantransplantation. Ophthalmologe. 18. Mai 2013;110(7):675–80.
Kotomin I, Valtink M, Hofmann K, Frenzel A, Morawietz H, Werner C, u. a. Sutureless fixation of amniotic membrane for therapy of ocular surface disorders. PLoS ONE. 2015;10(5):e0125035.

Application of AC+

The medicinal product *AmnioClip-plus, cryopreserved, DGFG* has been approved by the Paul Ehrlich Institute (PEI) under the number PEI.G.11968.01.1.
The amniotic membrane is clamped in the ring system in such a way that, after application, the chorionic side lies on the surface of the eye to be treated. If desired, the reverse orientation can be ordered. The AC+ is inserted into the eye locally under drip anaesthesia. The size of the AC+ allows optimal positioning on the eye surface and prevents slippage. The treatment area should not exceed the size of the AC+ (inner diameter 16 mm). The AC+ can remain on the eye for up to 14 days. Repeated treatments are possible with a new AC+ for a further 14-day duration.

Package leaflet

- The AC+ is delivered deep-frozen in a sterile container and is individually customized for every procedure.
- The AC+ must be stored at temperatures below -60°C (freezer or on dry ice) until 30min prior to the surgery.
- The maximum storage time (with continuous temperature monitoring of the freezer) is three months from the date of manufacture and only if the AC+ has been transferred to a suitable -60°C freezer in the sterile container immediately after receipt.
- The AC+ must be used within six hours after thawing and must not be refrozen once thawing has begun.
- The medicinal product is intended for single use only. The contents of a package are intended exclusively for use on a single patient.