

International allocation

An introduction of AC+ to international locations is possible if the import is approved and all necessary documents are available. The tissue allocation and quality management offices 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 (< -60°C). The DGFG charges an expense allowance for the provision of the AC+ 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 web-based recipient database www.gewebetranplantation.de, by fax or e-mail, in urgent exceptional cases also by telephone.

Ordering options and delivery



www.gewebetranplantation.de
Recipient database with online account



+49 (0)511/563559-5200



vs@gewebenetzwerk.de



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

more information
can be found
on our homepage



The German Society for Tissue Transplantation (DGFG)

Since 1997, the DGFG organises 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, and 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 Act, which expressly prohibits trade in and profit from tissues.

The DGFG supports its 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 order tissue transplants from the DGFG. Foreign institutions can obtain tissue transplants if these are available in sufficient quantities.

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DEUTSCHE GESELLSCHAFT FÜR
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AmnioClip-plus cryopreserved

PEI.G.11968.01.1

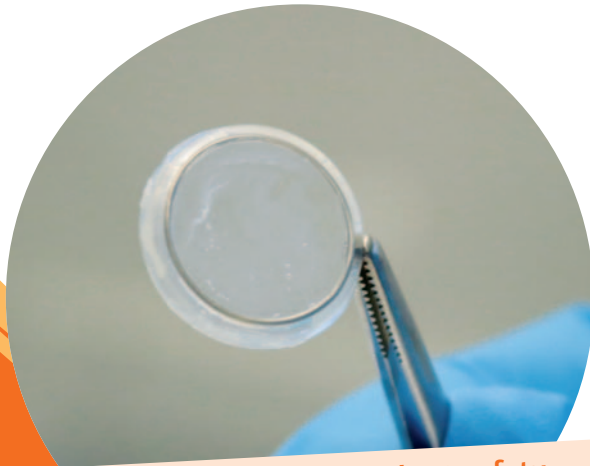


Application

In ophthalmology, the AmnioClip-plus (AC+) is used similarly to the amniotic membrane to treat eye surface disorders, to preserve the eye, and maintain or improve vision.

Indications for the use of the AC+:

- 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
- Dry eye syndrome
- High-risk keratoplasty for limbal stem cell deficiency



Amniotic membrane 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) has respective permissions in accordance with § 20 b and § 20 c of the German Medicinal Products Act. Each tissue donation is documented and traceable from consent to processing and transplantation.

About the Amnion

The human amniotic membrane (hAM) is the tissue surrounding the foetus in utero consisting of epithelium and stroma.

hAM can be easily extracted and preserved. Immunotolerance, promotion of epithelialisation, anti-inflammatory, anti-angiogenic, antifibroblastic and antimicrobial properties characterize the hAM. The freezing of fresh samples during the production of AC+ preserves the characteristics of the hAM better than freeze dried sample collection methods.

The hAM 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 hAM is processed at clean room conditions and subjected to extensive quality controls.

Advantages compared to conventional amniotic membrane transplantation (AMT)

AC+ eliminates the need for suturing procedures associated with AMT, therefore avoiding surgical trauma.

More advantages:

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



Literature/Sources

Engelmann K, Kotomin I, Knipper A, Werner C. Nahtlose Amnionmembrantransplantation. *Ophthalmologie*. 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 tissue preparation *AmnioClip-plus, cryopreserved, DGFG* has been approved by the Paul Ehrlich Institute (PEI) under the number PEI.G.11968.01.1.

The hAM 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 onto the eye locally under drip anaesthesia. 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.

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) and is thawed approx. 30min prior to the surgery.
- The maximum storage time (with continuous temperature monitoring) is one year from the date of preparation of the amniotic membrane 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 AC+ is intended for single patient use only.