

Amnitrans Eyebank / Hoornvliesbank - Algemene voorwaarden

GENERAL TERMS AND CONDITIONS OF DELIVERY

AMNITRANS EYEBANK ROTTERDAM

1 Definitions

1.1 Contractor: the foundation Amnitrans Eyebank Rotterdam.

1.2 Client: ophthalmologist, clinic or intermediary institute.

1.3 Services include: a) work relating to the receipt, processing, packaging, typing, screening and supply of Body Material and b) acting as an intermediary with respect to the supply, preservation, processing, storage, testing, assessment and distribution of Body Material, as well as c) activities connected therewith and relating to the provision of information, training and the development and application of knowledge.

1.4 Body Material: the component parts of the human body in the broadest sense of the word

1.5 Donor: a living or deceased person who has given permission, or on whose behalf permission has been given, to remove Body Material from his or her body for Implantation.

1.6 Implantation: the insertion or application of Body Material into or to the body of someone else (Recipient) with a view to his or her treatment for medical reasons.

1.7 Recipient: a (potential) recipient of Donor Body Material.

1.8 Third Party Organ bank: a party, not being Contractor, who supplies Body Material to the Contractor.

2 Applicability of the general conditions

2.1 The Client has read and understood these General Terms and Conditions and accepts their application to all (future) offers, deliveries, services, including the Services as defined herein, and agreements by or with the Contractor, brought about in any form whatsoever.

2.2 Deviations of these General Terms and Conditions must have been agreed upon in writing. However, the Contractor reserves the right to amend these General Terms and Conditions unilaterally. In that case the amended conditions shall take effect thirty (30) days after written notification to the Client, unless the Client objects in writing to the amended conditions within that period.

2.3 No General Terms and Conditions (apart from these of the Contractor), agreements or arrangements shall be considered agreed upon unless the Client has confirmed them in writing and the Contractor has accepted them in writing.

3 Agreement

3.1 An agreement shall only be concluded by means of a written order or registration of a Recipient by (or on behalf of) the Client, or written confirmation by the Contractor. The Client will use the tissue order form available on the Contractor's website and submit it fully filled in, dated and signed.

3.2 If the Contractor deems this necessary, payment guarantee may be required in advance.

4 Nature and extent of Services

4.1 The Contractor shall render the Services for the purpose of Implantation by the Client.

4.2 The Contractor shall endeavor to transport the Body Material under conditions that reasonably guarantee the quality of the Body Material all this in accordance with the latest state of science.

4.3 Delivery of the Body Material is at the Client's risk from the moment the Body Material is handed to the courier.

5 Necessary permits and permissions

In the performance of this agreement and specifically with respect to the receipt, storage and Implantation of the Body Material, the Client shall be obliged to act in accordance with all relevant national legislation, EU legislation and – where applicable – to ensure all necessary permits and permissions with regard to the import, receipt, storing and Implantation of the Body Material.

6 Supply of information to the Recipient

The Client shall see to it that, prior to the Implantation, also in conformity with the relevant legislation and regulations on the subject, the Recipient is informed about the advantages and disadvantages of the proposed Implantation. The recipient should be informed that, thanks to the stringent virological screening and bacteriological investigations to which the prepared tissue has been subjected, the risk of an infectious disease being transmitted has been minimized in accordance with the pertinent regulations, but cannot be excluded, for example where an unknown source of infection is concerned, or one, which cannot be detected with current technology.

7 Supply of information to the Contractor

7.1 The Client is obliged to report serious adverse events and serious adverse reactions concerning the supplied Body Material to the Contractor immediately.

7.2 The Client must provide the Contractor with all the relevant information in order to facilitate traceability and to guarantee quality control and safety for the Body Material supplied. For this purpose the Contractor shall provide a standard response notification form to the Client. The Contractor will collect follow up data from the Recipients at least at the time points 1-3 days after Implantation, 6 months and 1 year post-operative.

8 Supply of information to the Client

8.1 The Contractor shall provide information to the Client immediately in case of problems (subsequent laboratory results, autopsy results), thus ensuring a written documented quality system is in place.

8.2 In the event the Body Material has been supplied to the Contractor by a Third-Party Organ Bank at the request of the Client, then the Client will ensure that such Third-Party Organ Bank will provide information to the Client and the Contractor immediately in case of problems (subsequent laboratory results, autopsy results), thus ensuring a written documented quality system is in place.

9 Data recording

The Client is obliged to record relevant data, at least the identification code of the Body Material, in the patient status, so that the origin of the Body Material implanted in the Recipient can always be determined, for the time span that is laid down in Dutch legislation (30 years). The Contractor shall be entitled to check by means of random tests whether this record has been made properly.

10 Price and price changes

10.1 Unless agreed otherwise in writing, the fee for the Services will be determined on the basis of the Contractor's list of fees drawn up at regular intervals. Transport and handling costs will also be charged.

10.2 If after the conclusion of an agreement circumstances occur which necessitate an increase of the fees, the Contractor is entitled to pass on the relevant increases to the Client with immediate effect. The Client is entitled to subsequently abrogate the agreement if the price increase occurs within three months after the conclusion of the agreement.

11 Payment

11.1 The Client is obliged to pay the invoice sent by the Contractor with regard to the Services performed by the Contractor and the relevant Third Party Organ Bank within twenty-one (21) days after the date of the invoice, unless something else has been explicitly agreed in writing between the parties.

11.2 If the Client does not agree with (parts) of the invoice, he should inform the Contractor within ten (10) days after the date of the invoice.

11.3 The Client is obliged to make payment (effectively) in euros and any currency conversion charges and costs of money transfer will be upon Client.

11.4 The Client shall not be empowered to refuse payment because of the fact that no purchase or order number was stated when the order was given to the Contractor.

11.5 The Client is obliged to pay the invoice irrespective of whether the Body Material actually has been or will be used for Implantation.

11.6 The Client is obliged to pay the invoice if the Client cancels the order while the Body Material has already been shipped.

11.7 If a surgical predissection of Body Material which was sent to the Contractor by a Third-Party Organ Bank fails by Contractor's mistake, the surgical predissection costs will not be invoiced to the Client. However, the Third Party Organ Bank is allowed to invoice the Client for his processing and shipment

costs if they agreed upon this with the Client. If the quality of the received Body Material does not meet the Contractor's minimal standards, the Contractor will confer with the Third Party Organ Bank to return the tissue.

11.8 If the Client does not pay the amounts due within the period agreed upon, the statutory interest rate will apply. Besides, the Contractor shall be entitled to be compensated by the Client for all costs that the Contractor makes, both in and out of court, in connection with the collection of the claim.

12 Refusal of order

The Contractor shall at any rate be empowered to refuse an order if he, in view of invoices still outstanding, has grounds to fear that the Client will not fulfil payment obligations.

13 Client's own use

Without the Contractor's prior written permission the Client is not permitted to make the Body Material available to third parties or use it for other purposes than Implantation.

14 Expertise of the Client

The Client guarantees that the implanting ophthalmologist has the necessary medical expertise and knowledge necessary for skillful Implantation of the Body Material made available in the manner intended by the Client.

15 Force majeure

15.1 In these general conditions force majeure is any circumstance, foreseen or unforeseen, that cannot be imputed to the Contractor, as a result of which the Contractor is not able to fulfil his obligations in full or in part.

This shall at any rate include: strike of work, sit-in, government measures, power failures, breakdowns in electronic lines of communication, extreme weather and traffic conditions, fire, explosion and other calamities.

15.2 In the event of force majeure the Contractor shall be empowered to suspend the fulfilment of his obligations and to continue to do so as long as the force majeure situation continues. The Client shall not be empowered to terminate the agreement until after that force majeure situation has continued for two months.

16 Liability

16.1 The Client must notify the Contractor of an obvious non-conformity of the Body Material promptly and ultimately within 48 hours of receipt of the Body Material, in writing. Failing to do so will deprive the

Client of any rights to make any claim for damages or specific performance with respect to such non-conformity.

16.2 Without prejudice to the foregoing, the Client shall forfeit any right to claim damages or specific performance, on the basis of a non-conformity of the Body Material, if the Client has not, within an adequate period after he could reasonably have discovered such non-conformity, made a documented notification to the Contractor of the non-conformity.

16.3 Any claims for damages or specific performance on the basis of non-conformity can only be made if, after consulting the Contractor, the Client returns the Body Material, promptly after the discovery of the non-conformity, in its original packaging and properly preserved, to the Contractor, unless otherwise agreed between the Contractor and the Client in writing. All claims of the Client for damages or specific performance shall be forfeited 3 months after delivery of the Body Material.

16.4 The Contractor will not be liable for any damages arising out of its obligations under this agreement, except for gross negligence and willful misconduct. Without prejudice to his obligation under this agreement to use best efforts to have the Body Material procured, preserved, stored and transported in accordance with the EU Regulations and Directives and pertinent Dutch legislation, the Contractor provides the Body Material to the Client "as is", i.e. a biological material from a human source, destined for transplantation by the Client in a Recipient, and the Contractor specifically disclaims all liability arising from unknown sources of infection of the Body Material or sources which cannot be detected with current technology, or from the Body Material being unfit for the Recipient concerned or from incorrect transplantation of the Body Material or from post-transplantation care of the Recipient. The liability for determining whether the Recipient is fit to receive the Body Material concerned lies with the Client.

16.5 The Client shall indemnify and hold the Contractor harmless from any third party claims in respect of the Body Material.

16.6 In the event of a non-conformity of the Body Material, the Contractor's liability is primarily limited to resupplying the Client with a new Body Material. In the event any non-conformity is due to a non-conformity in the procurement, supply, transport and/or delivery by a Third Party Organ Bank to the Contractor, Contractor shall not be liable for any damages suffered by the Client or Recipient as a result of such non-conformity and Contractor shall address any action for liability to such Third Party Organ Bank exclusively and directly.

16.7 Any liability of the Contractor is at all times limited to the amount that in the case concerned will be actually paid out under the Contractor's liability insurance policy. The Contractor's liability for damages on account of a claimed non-conformity in the Body Material shall in no event exceed the amount invoiced by the Contractor for the Body Material involved.

16.7 In no event shall the Contractor be liable to the Client or to any third parties and the Client will indemnify and hold harmless the Contractor in case of a claim by third parties, including but not limited to claims by the Recipient, for any consequential (indirect), incidental, punitive, contingent, statutory or

any other special damages (including without limitation loss of profits) arising out of or related to the agreement, whether in contract, tort, or otherwise. 16.8 The Client shall have in place at all times sufficient liability insurance, covering both direct and indirect damages, for his activities with and transplantation of the Body Material.

17 Final determination

If single definitions of the agreement are invalid or ineffective, the other definitions are not influenced by that. In fact, the respective valid national legal definitions will replace the invalid or ineffective definitions.

Both parties oblige themselves in case of disagreement to attain a consensus. This agreement is governed by Dutch law and the competent court in case of disputes based on this agreement is the Rotterdam district court.