

STANDARD TERMS AND CONDITIONS

Acceptance: Bio-Tissue, Inc. (Bio-Tissue) will send Customer a Pricing Confirmation Letter (PCL) outlining all Products and Prices that Bio-Tissue is offering Customer. Customer's (i) full or partial performance under, or indication thereof; or, (ii) acknowledgement of the PCL is acceptance of all terms and conditions contained in the document, including these Terms and Conditions (T&C).

Prices: The prices provided to Customer are for Customer's exclusive use and benefit. Prices for Products will remain set for the duration of Customer's PCL.

Payment: Billing – Bio-Tissue will bill Customer directly for all orders that are accepted by Bio-Tissue. All payments made by Customer shall be made directly to Bio-Tissue. Checks should be made payable to Bio-Tissue, Inc.
Shipping Terms – All Products are shipped standard overnight at no extra charge to Customer.

Notices: Unless agreed in writing by the parties hereto, all communications will be in writing and will be deemed delivered if: (i) given in person, (ii) received by facsimile or overnight courier on the next business day, or (iii) received within five (5) business days after being sent by first-class mail, registered or certified, return receipt requested, with proper postage prepaid to 7300 CORPORATE CENTER DRIVE, SUITE 700, MIAMI FL 33126.

Risk of Loss: Risk of loss will be on Bio-Tissue until products have been delivered to Customer's address. Customer will be allowed 3 business days to inspect the products and to notify Bio-Tissue of any missing or damaged product, or other non-conformance within the terms and conditions of the Order. Failure to report damaged or non-conforming products within the set period will be deemed Customer's acceptance of Products.

Title: Consignment – Title to all Consigned Products delivered to Customer shall remain with Bio-Tissue until such Products are used and Customer issues Bio-Tissue a Purchase Order. Products on consignment shall be deemed to be outstanding until they are paid for in full by Customer.

End User - Title to all Products shall transfer to Customer after Products have been delivered to Customer at Customer's address and Customer has accepted Products. Unless Customer gives Bio-Tissue written notice within 3 business days of receipt to dispute non-conforming Products delivered, Products will be deemed accepted by Customer and Title will transfer to Customer.

Consigned Products: Once the Product is used, Customer will return the Donor & Recipient Information Card (which contains the product serial number and associated transplant information). Customer shall call the Customer Service Department and supply a Purchase Order to authorize Bio-Tissue to bill and replace the product. Customer will allow Bio-Tissue, its agents, employees, or representatives to perform periodic quality and quantity review of the consigned Product.

Returns: Bio-Tissue does not accept any returns, other than Products in excess of the number Customer orders or damaged or non-conforming Product when Customer notifies Bio-Tissue within 3 business days of receipt of the damaged Product.

Limited Warranty; Remedy: If stored properly, shelf life of Product is as set forth in the table below. For any Products found to be defective, this warranty provides and is restricted to either (i) replace the Product within a reasonable time without any charge to Customer; or, (ii) refund or credit Customer in the amount of the purchase price of the Product. Bio-Tissue will bill Customer for the Price of the defective Product if Customer does not return the defective Product to Bio-Tissue within 10 days after Bio-Tissue ships the replacement Product. **THIS WARRANTY IS THE SOLE WARRANTY PROVIDED BY BIO-TISSUE. ALL OTHER WARRANTIES OF ANY KIND, INCLUDING WARRANTIES OF MERCHANTABILITY, SATISFACTORY QUALITY, AND FITNESS FOR A PARTICULAR PURPOSE ARE EXCLUDED TO THE FULLEST EXTENT PERMITTED BY LAW.**

Storage: It is the responsibility of Bio-Tissue, Tissue Distribution Intermediary, and End-User to maintain Product in appropriate storage conditions prior to further distribution or transplant. Customer accepts responsibility for properly storing all Products according to Bio-Tissue published storage guidelines.

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After receipt, store PROKERA® accordingly until time of use:

Location & Temperature	Use After Receipt
Unopened insulated shipping container	Within the expiration date printed on outer shipping box
-80°C → 4°C (-112°F → 39.2°F) Example: ultra-low temperature freezer, standard freezer, or standard refrigerator	Within the expiration date printed on product packaging (shelf-life is 2 years from date of manufacture)

Quality: Customer agrees to: (a) cooperate with and assist in Bio-Tissue Quality Department’s audit of Customer’s facilities; (b) implement any changes reasonably requested by Bio-Tissue as a result of such audit; and, (c) enter into a mutually acceptable quality agreement with Bio-Tissue. Either party may terminate the Agreement with immediate effect if such party determines that the Parties will not accomplish all of clauses (a), (b) and (c) within a reasonable timeframe.

Compliance with HIPAA: The parties agree to cooperate fully and promptly comply with the Standards for Privacy of Individually Identifiable Information under the Health Insurance Portability and Accountability Act of 1996 contained in 45 CFR Parts 160 and 164 (the “HIPAA Privacy Standards”) as of the effective date of the HIPAA Privacy Standards on April 14, 2003, or as later determined, if applicable, including without limitation entering into a mutually acceptable Business Associate Agreement.

Traceability, Adverse Reaction/Deviations Investigation and Reporting: Bio-Tissue shall investigate all complaints and report to all applicable Regulatory Bodies (e.g. FDA, AATB) any adverse reactions from the end user or recipient that is fatal, life threatening, results in permanent impairment of a body function or necessitates medical, or surgical intervention including hospitalization. Nothing herein shall be construed as to restrict Customer from investigating or reporting adverse reactions and deviations.

Recalls, Notifications, Tracking: Bio-Tissue shall be responsible for conducting any withdrawals, recalls, notification or tracking of Products. Customer shall cooperate and assist Bio-Tissue in any investigation, withdrawals, recall, notification, or tracking initiated by Bio-Tissue involving any Products.

Retention and Inspection of Records: Each party shall keep all records relevant to this Agreement on file for a period of ten (10) years from the expiration date of the products. Each Party shall, upon reasonable notice, give the other party or its authorized representative the privilege of inspecting, examining, and auditing, at a reasonable time during normal business hours, such business records which are directly relevant to the financial arrangements under this T&C. The cost of such inspection, examination, and audit will be at the sole expense of the party conducting such inspection, investigation and/or audit and such inspection, examination, and audit shall be conducted where said records are normally maintained.

Confidentiality: Customer will not directly or indirectly disclose the prices in the PCL to a third party. Information received under this Agreement shall not be mechanically or electronically copied or otherwise reproduced by Customer without the written consent of Bio-Tissue. The confidentiality obligations of Customer, will survive the termination or expiration of Customer’s Agreement.

Modification: Any modifications will not be effective unless agreed to in writing by both parties and properly executed.

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Integrated Agreement: This T&C supersedes and terminates any and all previous Agreements of whatever nature between Bio-Tissue and Customer with respect to the matters covered herein. This constitutes the full, complete and exclusive agreement between Bio-Tissue and Customer with respect to the subject matter herein.

Severability: If any provision of the T&C is declared invalid, illegal or unenforceable, such provision will be severed and all remaining provisions will continue in full force and effect.

Governing Law: This T&C shall be governed by and construed in accordance with the laws of the State of Florida, without regard to the conflicts of law principles thereof.

Titles: The titles and subtitles used in this T&C are used for convenience only and are not to be considered in construing or interpreting this T&C.

Assignment: Neither party may assign or otherwise transfer all or any part of its rights and/or obligations under this Agreement to any third party without the other party's prior written consent, except in connection with the acquisition of all the stock and/or assets of such party by the third party. Any purported assignment or other transfer lacking such consent or absent such acquisition shall be of no effect.

Relationship of the Parties: The relationship between Bio-Tissue and Customer will be that of independent contractor and not Principal and agent. Neither Party will represent itself as an agent or legal partner of the other Party, nor perform any action that might result in other persons believing that it has any authority to bind or enter into commitment on behalf of the other.

Indemnification: Customer agrees to indemnify, hold harmless and defend Bio-Tissue (and its employees, affiliates, successors, and agents) from and against any and all claims (whether based on contract, tort, strict liability or otherwise), judgments, liabilities, damages, losses, expenses and costs (including, but not limited to, court costs and attorneys' fees) incurred or suffered by Bio-Tissue, which relate to or arise out of (i) Customer's use, handling, sale, distribution or disposal of the products, or (ii) Customer's breach of any representation or obligation hereunder. Customer shall defend any such matter with counsel reasonably acceptable to Bio-Tissue and shall not settle any such matter except with the consent of Bio-Tissue which consent shall not be unnecessarily withheld. If Customer fails to promptly and diligently investigate and defend or settle any claim, then Bio-Tissue shall have the right, at Customer's cost, expense and risk, from that time forward to have sole control of the defense of the claim and the terms of any settlement or compromise.