

TISSUE TRACEABILITY AND UTILIZATION RECORD

REQUIRED FOR ALL HUMAN TISSUE ALLOGRAFTS

Tissue Label

Facility Information

Facility	
Address	
City, State, Zip	
Phone	

Physician Information

Physician	
Department	

Patient Information

(Do Not Include Patient Name)

Patient Identifier	
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Procedure Performed Information

Procedure	
Surgical Site	
Date of Implantation	

I certify that the above information is accurate and complete.

Signature: _____

MUST BE COMPLETED AND RETURNED AFTER USE

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RETURN INSTRUCTIONS

A product identification sticker has already been affixed to this Tissue Traceability and Utilization Record to capture the required graft information. After implantation or discard of the allograft, please complete the remaining fields, including the patient identifier and procedure date, and return this form using one of the methods listed below. Scanning and emailing the completed form is preferred for timely confirmation.

Returning this form is important to maintain complete traceability of human tissue allografts in accordance with federal regulations and accreditation standards. Accurate traceability supports patient safety, enables timely communication in the event of a product notice or recall, and helps ensure compliance with FDA and Joint Commission requirements.

To protect patient privacy, please include only the requested patient identifier and do not include the patient's full name or additional protected health information.

Please return the completed Tissue Traceability and Utilization Record using one of the methods below. **Email is preferred** for timely confirmation of tissue disposition.

Email (Preferred):

traceability@biomed-ent.com

Mail:

BioMed ENT, Inc.
757 North Water Street, Suite 300
Milwaukee, Wisconsin 53202

Fax:

(210) 855-3872

If you have any questions regarding this form or traceability requirements, please contact BioMed ENT at (414) 616-1172.