CHANGES TO AATB STANDARDS FOR TISSUE BANKING

SECTION G - LABELING

G3.000 LABELING INFORMATION

G3.200 Summary of Records and Package Insert

Current (13th edition)
G3.220 Package Insert Content
The *Summary of Records* may be included in the *Package Insert*. The *Package Insert* shall contain the following information:

1) A statement limiting use to specific health professionals (e.g., physicians, dentists, and/or podiatrists);

2) A statement that the tissue is intended for use in one patient, on a single occasion only, or as is applicable for *Reproductive Tissue*;

3) Known contraindications (if any) to the use of the tissue;

4) Warnings and list of known possible significant adverse reactions;

5) A statement that *Adverse Outcomes* potentially attributable to the tissue must be reported promptly to the tissue supplier;

6) Presence of known sensitizing agents (if any);

7) A statement that indicates that the tissue may transmit infectious agents;

8) A statement, if applicable, that the tissue may not be *Sterilized* or re-sterilized.

9) Dosage information (if applicable);

10) Description of how the tissue was supplied (e.g., frozen, lyophilized, irradiated);

11) Type of antibiotics present (if applicable);

12) Concentration of preservative(s) and/or cryoprotectant(s) in final package solution(if applicable);

13) Instructions for opening the *Package* and/or *Container*;

14) Instructions for preparation of tissue for transplantation;

15) Expiration time of tissue following reconstitution;

16) Instructions indicating that once a *Container* seal has been compromised, the tissue shall be either transplanted, if appropriate, or otherwise discarded;

17) Recommended acceptable storage conditions and *Tolerance Limits*;

18) Special instructions required for the particular tissue (e.g., ‘‘DO NOT FREEZE’’);

19) A statement that it is the responsibility of the *Tissue Dispensing Service, Tissue Distribution Intermediary,* and/or *End-User* clinician to maintain tissue intended for transplantation in appropriate storage conditions prior to further *Distribution* or transplant and that *Recipient* records must be maintained for the purpose of tracing tissue post-transplantation;

20) A statement that the tissue is ‘‘DONATED HUMAN TISSUE,’’ when applicable; and

21) Effective date or other traceable version identifier.

(with amendments)

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11) Type of antibiotics present (if applicable);

12) Concentration of preservative(s) and/or cryoprotectant(s) in final package solution(if applicable);

13) Instructions for opening the *Package* and/or *Container*;

14) Instructions for preparation of tissue for transplantation;

15) Expiration time of tissue following reconstitution *(upon preparation for use)*;

16) Instructions indicating that once a *Container* seal has been compromised, the tissue shall be either transplanted, if appropriate, or otherwise discarded;

17) ~~Recommended~~ ~~a~~*A*cceptable storage conditions and *Tolerance Limits*;

18) Special instructions required for the particular tissue*, when applicable* (e.g., ‘‘DO NOT FREEZE,’’ *“DO NOT X-RAY,” “DO NOT IRRADIATE”*);

19) A statement that it is the responsibility of the *Tissue Dispensing Service, Tissue Distribution Intermediary,* and/or *End-User* clinician to maintain tissue intended for transplantation in appropriate storage conditions prior to further *Distribution* or transplant and that *Recipient* records must be maintained for the purpose of tracing tissue post-transplantation;

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(as amended)

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13) Instructions for opening the *Package* and/or *Container*;

14) Instructions for preparation of tissue for transplantation;

15) Expiration time of tissue following reconstitution (upon preparation for use);

16) Instructions indicating that once a *Container* seal has been compromised, the tissue shall be either transplanted, if appropriate, or otherwise discarded;

17) Acceptable storage conditions and *Tolerance Limits*;

18) Special instructions required for the particular tissue, when applicable (e.g., ‘‘DO NOT FREEZE,’’ “DO NOT X-RAY,” “DO NOT IRRADIATE”);

19) A statement that it is the responsibility of the *Tissue Dispensing Service, Tissue Distribution Intermediary,* and/or *End-User* clinician to maintain tissue intended for transplantation in appropriate storage conditions prior to further *Distribution* or transplant and that *Recipient* records must be maintained for the purpose of tracing tissue post-transplantation;

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21) Effective date or other traceable version identifier.

Publication date: November 12, 2013 (AATB Bulletin No. 13-18)
Effective date: February 10, 2014 (in 90 days)