



# THE NATIONAL TISSUE RECOVERY THROUGH UTILIZATION SURVEY

## SECTION 4 - Tissue Processing

The Office of the Assistant Secretary for Health, Department of Health and Human Services (HHS), through a contract with the American Association of Tissue Banks, is conducting the 2016 National Tissue Recovery through Utilization Survey (NTRUS).

XXXXX

Your responses will remain anonymous in the final dataset. While results of this survey will be released in aggregate form and data may be made available in the form of a de-identified dataset, no specific institutional identifiable information will be included.

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0990-xxxx. The time required to complete this information collection is estimated to average 60 minutes per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: U.S. Department of Health & Human Services, OS/OCIO/PRA, 200 Independence Ave., S.W., Suite 336-E, Washington D.C. 20201, Attention: PRA Reports Clearance Officer

## Tissue Processing

The survey provides definitions for specific donors and tissue types. To facilitate accurate totals, provide counts using the descriptions provided. Where terms are *italicized*, use the definitions found at AATB Standard A2.000 DEFINITIONS OF TERMS. Some terms and/or definitions are new and some have been revised. Refer to the NTRUS Definitions of Terms document provided with this survey.

The information you are reporting is for the following physical locations(s) by name, city and state:

A. name, city, state

B. name, city, state

(need capability for multiple lines/entries)

Which of the following types of *tissue* did your *tissue bank* process? (Check all that apply)

### TISSUE FROM DECEASED DONORS

- musculoskeletal (i.e., bone, cartilage, osteochondral grafts, osteoarticular grafts)
- soft tissue (i.e., fascia lata, ligaments, tendons, pericardium, nerves, peritoneal membrane, adipose)
- cardiac tissue*
- vascular tissue*
- skin*
- cellular tissue*
- dura mater*
- other *tissue* from deceased donors (specify) \_\_\_\_\_

How many total deceased donors did your *tissue bank* process? (count one donor only once) \_\_\_\_\_

What is the average graft yield (#) per deceased donor (for all *tissue* types combined)? \_\_\_\_\_

Note: Graft yield is defined as the total number of *finished tissue* grafts processed from one donor.

### TISSUE FROM LIVING DONORS

- living donor tissue* (i.e., *birth tissue*, *surgical bone*, *skin* for *allogeneic* use, or *autologous* bone)
- other *tissue* from *living donors* (specify) \_\_\_\_\_

How many total *living donors* did your *tissue bank* process? (count one donor only once) \_\_\_\_\_

What is the average graft yield (#) per living donor (for all *tissue* types combined)? \_\_\_\_\_

Note: Graft yield is defined as the total number of *finished tissue* grafts processed from one donor.

How many total donors of the following types of *tissues* did your *tissue bank* process:

## TISSUE FROM DECEASED DONORS

### musculoskeletal

bone \_\_\_\_\_

cartilage (e.g., costal, articular) \_\_\_\_\_

osteocondral grafts - **fresh/refrigerated** \_\_\_\_\_ (i.e., an *allograft* consisting of a section, condyle, or plug of bone with an intact articular surface)

osteocondral grafts - **frozen/cryopreserved** \_\_\_\_\_ (i.e., an *allograft* consisting of a section, condyle, or plug of bone with an intact articular surface)

osteoarticular grafts - **fresh/refrigerated** \_\_\_\_\_ (i.e., a large weight bearing *allograft* with intact articular surfaces consisting of a joint with associated soft tissue and bone)

osteoarticular grafts - **frozen/cryopreserved** \_\_\_\_\_ (i.e., a large weight bearing *allograft* with intact articular surfaces consisting of a joint with associated soft tissue and bone)

### soft tissue

fascia lata \_\_\_\_\_

ligaments (i.e., patellar) \_\_\_\_\_

tendons (e.g., Achilles, gracillis, anterior/posterior tibialis, semitendinosus, flexors/extensors, peroneus longus) \_\_\_\_\_

rotator cuff \_\_\_\_\_

pericardium \_\_\_\_\_

nerves \_\_\_\_\_

peritoneal membrane \_\_\_\_\_

adipose \_\_\_\_\_

### cardiac tissue

valved conduits \_\_\_\_\_

non-valved conduits \_\_\_\_\_

patch graft \_\_\_\_\_

aortoiliac graft \_\_\_\_\_

vascular tissue

arteries \_\_\_\_\_

vein grafts \_\_\_\_\_

skin

thin \_\_\_\_\_

thick \_\_\_\_\_

full-thickness \_\_\_\_\_

cellular tissue \_\_\_\_\_

dura mater \_\_\_\_\_

tissue as a device \_\_\_\_\_

(i.e., products and combination products requiring PMA or 510k clearance; regulated under the FD&C Act as well as under 21 CFR Part 1271 from Section 361 of the PHSA)

tissue as a biological product \_\_\_\_\_

(i.e., products requiring BLA or IND; regulated under Section 351 of the PHSA and/or the FD&C Act, as well as under 21 CFR Part 1271 from Section 361 of the PHSA)

tissue as a drug \_\_\_\_\_

(i.e., products requiring IND/NDA; regulated under Section 201 of the FD&C Act, as well as under 21 CFR 1271 from Section 361 of the PHSA)

other tissue from deceased donors (specify) \_\_\_\_\_ ; indicate number for each \_\_\_\_\_

**How many donors of the following types of *tissues* did your *tissue bank* process:**

**TISSUE FROM LIVING DONORS**

*birth tissue*

amniotic membrane (only) \_\_\_\_\_

chorionic membrane (only) \_\_\_\_\_

amniotic + chorionic membrane \_\_\_\_\_

amniotic fluid \_\_\_\_\_

Wharton's jelly \_\_\_\_\_

placental/chorionic disc \_\_\_\_\_

umbilical cord tissue \_\_\_\_\_

umbilical vein \_\_\_\_\_

other *birth tissue* (specify) \_\_\_\_\_; indicate number for each \_\_\_\_\_

*surgical bone* \_\_\_\_\_

*skin for allogeneic use* \_\_\_\_\_

*autologous bone* \_\_\_\_\_

*autologous parathyroid* \_\_\_\_\_

*tissue as a device* \_\_\_\_\_

(i.e., products and combination products requiring PMA or 510k clearance; regulated under the FD&C Act as well as under 21 CFR Part 1271 from Section 361 of the PHSA)

*tissue as a biological product* \_\_\_\_\_

(i.e., products requiring BLA or IND; regulated under Section 351 of the PHSA and/or the FD&C Act, as well as under 21 CFR Part 1271 from Section 361 of the PHSA)

*tissue as a drug* \_\_\_\_\_

(i.e., products requiring IND/NDA; regulated under Section 201 of the FD&C Act, as well as under 21 CFR 1271 from Section 361 of the PHSA)

*other tissue* from *living donors* (specify) \_\_\_\_\_; indicate number for each \_\_\_\_\_

**How does your *tissue bank* treat *tissues* with radiation PRIOR to processing (non-terminal irradiation)? Check all that apply.**

- we do not treat *tissues* with radiation prior to *processing*
- electron beam radiation only; indicate dose: \_\_\_\_\_
- gamma radiation only, below 1.5 Mrads (15 kGy)
- gamma radiation only, 1.5 - 2.5 Mrads (15-25 kGy)
- gamma radiation only, above 2.5 Mrads (25 kGy)

**How does your *tissue bank* treat *tissues* with radiation to reduce/eliminate microorganisms as a FINAL treatment (terminal irradiation)? Check all that apply.**

- we do not treat *tissues* with radiation as a final treatment
- electron beam radiation only; indicate dose: \_\_\_\_\_
- gamma radiation only, below 1.5 Mrads (15 kGy)
- gamma radiation only, 1.5 - 2.5 Mrads (15-25 kGy)
- gamma radiation only, above 2.5 Mrads (25 kGy)

**Indicate how many musculoskeletal GRAFTS were processed using the following methods (if none, enter zero):**

electron beam radiation (only) \_\_\_\_\_

gamma radiation (only) \_\_\_\_\_

ethylene oxide (only) \_\_\_\_\_

antibiotics (only) \_\_\_\_\_

Types of proprietary/patented processing (only)

Allowash® \_\_\_\_\_

ATP \_\_\_\_\_

BioCleanse® Process \_\_\_\_\_

Clearant Process® \_\_\_\_\_

Tutoplast® Process \_\_\_\_\_

NovaSterilis (supercritical CO2) \_\_\_\_\_

Other proprietary methods (specify) \_\_\_\_\_; indicate number \_\_\_\_\_

Combinations of Antibiotics and Radiation - Musculoskeletal

For each combination used specify antibiotic(s), radiation target dose (below 1.5 Mrads, between 1.5 and 2.5 Mrads, and above 2.5 Mrads) and number of grafts *processed* using these combination methods

Antibiotic(s) (specify)	Radiation Target Dose	# grafts
_____	_____	_____
_____	_____	_____

Combinations of Proprietary/Patented Processing then Radiation - Musculoskeletal

For each combination used please specify proprietary *processing* method, radiation target dose (below 1.5 Mrads, between 1.5 and 2.5 Mrads, and above 2.5 Mrads) and number of grafts *processed* using these combination methods

Proprietary/Patented Method (specify)	Radiation Target Dose	# grafts
_____	_____	_____
_____	_____	_____

Report any other combinations of methods used: \_\_\_\_\_

**Indicate how many soft tissue GRAFTS (i.e., fascia lata, ligaments, tendons, pericardium, nerves, peritoneal membrane, adipose) were *processed* using the following methods (if none, enter zero):**

electron beam radiation (only) \_\_\_\_\_

gamma radiation (only) \_\_\_\_\_

ethylene oxide (only) \_\_\_\_\_

antibiotics (only) \_\_\_\_\_

Types of Proprietary/Patented Processing (only)

Allowash® \_\_\_\_\_

ATP \_\_\_\_\_

BioCleanse® Process \_\_\_\_\_

Clearant Process® \_\_\_\_\_

Tutoplast® Process \_\_\_\_\_

NovaSterilis (supercritical CO2) \_\_\_\_\_

other proprietary methods (specify) \_\_\_\_\_; indicate number \_\_\_\_\_

Combinations of Antibiotics and Radiation – Soft Tissue Grafts

For each combination used please specify antibiotic(s), radiation target dose (below 1.5 Mrads, between 1.5 and 2.5 Mrads, and above 2.5 Mrads) and number of grafts processed using these combination methods

Antibiotic(s) (specify)	Radiation Target Dose	# grafts
_____	_____	_____
_____	_____	_____

Combinations of Proprietary/Patented Processing then Radiation – Soft Tissue Grafts

For each combination used please specify proprietary *processing* method, radiation target dose (below 1.5 Mrads, between 1.5 and 2.5 Mrads, and above 2.5 Mrads) and number of grafts *processed* using these combination methods

Proprietary/Patented Method (specify)	Radiation Target Dose	# grafts
_____	_____	_____
_____	_____	_____

Report any other combinations of methods used: \_\_\_\_\_

**Indicate how many *cardiac tissue* GRAFTS were preserved using the following methods (if none, enter zero):**

refrigerated only (i.e., provided for use as fresh) \_\_\_\_\_

controlled-rate electronic programmable freezing \_\_\_\_\_

other methods (specify) \_\_\_\_\_; indicate number \_\_\_\_\_

**Indicate how many units of *cardiac tissue* GRAFTS were *processed* into *finished tissue* for each of the following types (enter 0 if not applicable):**

acellular/decellularized: \_\_\_\_\_

NOT acellular/decellularized: \_\_\_\_\_



other type (specify) \_\_\_\_\_; indicate number \_\_\_\_\_

**Indicate how many *vascular tissue* GRAFTS were preserved using the following methods (if none, enter zero):**

refrigerated only (i.e., provided for use as fresh) \_\_\_\_\_

controlled-rate electronic programmable freezing \_\_\_\_\_

other methods (specify) \_\_\_\_\_; indicate number \_\_\_\_\_

**Indicate how many units of *vascular tissue* GRAFTS were *processed* into *finished tissue* for each of the following types (enter 0 if not applicable):**

acellular/decellularized: \_\_\_\_\_

NOT acellular/decellularized: \_\_\_\_\_

other type (specify) \_\_\_\_\_; indicate number \_\_\_\_\_

**Indicate how many *skin* GRAFTS were processed using the following methods (if none, enter zero):**

electron beam radiation (only) \_\_\_\_\_

gamma radiation (only) \_\_\_\_\_

ethylene oxide (only) \_\_\_\_\_

antibiotics (only) \_\_\_\_\_

Types of Proprietary/Patented Processing (only)

Allowash® \_\_\_\_\_

ATP \_\_\_\_\_

BioCleanse® Process \_\_\_\_\_

Clearant Process® \_\_\_\_\_

Tutoplast® Process \_\_\_\_\_

NovaSterilis (supercritical CO2) \_\_\_\_\_

other proprietary methods (specify) \_\_\_\_\_; indicate number \_\_\_\_\_

Combinations of Antibiotics and Radiation - Skin

For each combination used please specify antibiotic(s), radiation target dose (below 1.5 Mrads, between 1.5 and 2.5 Mrads, and above 2.5 Mrads) and number of grafts *processed* using these combination methods

Antibiotic(s) (specify)	Radiation Target Dose	# grafts
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\_\_\_\_\_  
\_\_\_\_\_

Combinations of Proprietary/Patented Processing then Radiation - Skin

For each combination used please specify proprietary *processing* method, radiation target dose (below 1.5 Mrads, between 1.5 and 2.5 Mrads, and above 2.5 Mrads) and number of grafts *processed* using these combination methods

Proprietary/Patented Method (specify)	Radiation Target Dose	# grafts
_____	_____	_____
_____	_____	_____

Report any other combinations of methods used: \_\_\_\_\_

**Indicate how many *birth tissue* GRAFTS were *processed* using the following methods (if none, enter zero):**

- electron beam radiation (only) \_\_\_\_\_
- gamma radiation (only) \_\_\_\_\_
- ethylene oxide (only) \_\_\_\_\_
- antibiotics (only) \_\_\_\_\_
- filtration (only) \_\_\_\_\_
- ultraviolet light (only) \_\_\_\_\_

Types of Proprietary/Patented Processing (only)

- Allowash® \_\_\_\_\_
- ATP \_\_\_\_\_
- BioCleanse® Process \_\_\_\_\_
- Clearant Process® \_\_\_\_\_
- Tutoplast® Process \_\_\_\_\_
- NovaSterilis (supercritical CO2) \_\_\_\_\_

Purion® Process \_\_\_\_\_

Cryotek™ Process \_\_\_\_\_

other proprietary methods (specify) \_\_\_\_\_; indicate number for each \_\_\_\_\_

Combinations of Antibiotics and Radiation - Birth Tissue Grafts

For each combination used please specify antibiotic(s), radiation target dose (below 1.5 Mrads, between 1.5 and 2.5 Mrads, and above 2.5 Mrads) and number of grafts *processed* using these combination methods

Antibiotic(s) (specify)	Radiation Target Dose	# grafts
_____	_____	_____
_____	_____	_____

Combinations of Proprietary/Patented Processing then Radiation - Birth Tissue Grafts

For each combination used please specify proprietary *processing* method, radiation target dose (below 1.5 Mrads, between 1.5 and 2.5 Mrads, and above 2.5 Mrads) and number of grafts *processed* using these combination methods

Proprietary/Patented Method (specify)	Radiation Target Dose	# grafts
_____	_____	_____
_____	_____	_____

Report any other combinations of methods used: \_\_\_\_\_

**For what applications does your *tissue bank* process demineralized bone (check all that apply)?**

- we do not process demineralized bone
- orthopedic surgery
- dental/periodontal procedures
- neurosurgery
- other applications (specify) \_\_\_\_\_

**Does your *tissue bank* process *skin* for use as fresh grafts (not cryopreserved)?**

- no, we do not *process skin*
- no, we *process skin*, but not for use as fresh grafts
- yes, we *process skin* for use as fresh grafts

**Indicate how much *skin* (in square feet) was preserved by each of the following methods (enter 0 if not applicable)**

refrigerated only \_\_\_\_\_  
controlled-rate electronic programmable freezing \_\_\_\_\_  
heat sink freezing method \_\_\_\_\_  
*lyophilized* \_\_\_\_\_  
dehydrated \_\_\_\_\_  
dessicated \_\_\_\_\_  
other methods (specify) \_\_\_\_\_; indicate number \_\_\_\_\_

**Indicate how much *skin* (in square feet) was processed into *finished tissue* for each of the following types (enter 0 if not applicable):**

acellular/decellularized: \_\_\_\_\_  
NOT acellular/decellularized: \_\_\_\_\_

**Indicate how many units of *birth tissue* were preserved using the following methods; this refers to the preservation method used only for *finished tissue* (enter 0 if not applicable)**

refrigerated only (i.e., provided for use as fresh) \_\_\_\_\_  
simple freezing \_\_\_\_\_  
controlled-rate electronic programmable freezing \_\_\_\_\_  
*lyophilized* \_\_\_\_\_  
dehydrated \_\_\_\_\_  
dessicated \_\_\_\_\_  
other methods (specify) \_\_\_\_\_; indicate number \_\_\_\_\_

**Indicate how many units of *birth tissue* were processed into *finished tissue* for each of the following types (enter 0 if not applicable):**

acellular/decellularized: \_\_\_\_\_

NOT acellular/decellularized: \_\_\_\_\_

**For what applications does your *tissue bank* process *birth tissue* (check all that apply)?**

- we do not process *birth tissue*
- ophthalmic
- leg/foot ulcers
- orthopedic
- dental/periodontal
- neurosurgical and spine
- burns
- general surgical
- other general uses (specify) \_\_\_\_\_

**Indicate how many donors of *skin* were *recovered* by the following:**

AATB-accredited OPOs/*tissue banks* \_\_\_\_\_  
non-AATB accredited OPOs/*tissue banks* \_\_\_\_\_  
health care facilities (e.g., hospital or surgical center) \_\_\_\_\_

**Indicate how many donors of *musculoskeletal tissue* were *recovered* by the following:**

AATB-accredited OPOs/*tissue banks* \_\_\_\_\_  
non-AATB accredited OPOs/*tissue banks* \_\_\_\_\_  
health care facilities (e.g., hospital or surgical center) \_\_\_\_\_

**Indicate how many donors of *soft tissue* were *recovered* by the following:**

AATB-accredited OPOs/*tissue banks* \_\_\_\_\_  
non-AATB accredited OPOs/*tissue banks* \_\_\_\_\_  
health care facilities (e.g., hospital or surgical center) \_\_\_\_\_

**Indicate how many donors of *cardiac tissue* or *vascular tissue* were recovered by the following:**

*cardiac tissue*

AATB-accredited OPOs/*tissue banks* \_\_\_\_\_

non-AATB accredited OPOs/*tissue banks* \_\_\_\_\_

health care facilities (e.g., hospital or surgical center) \_\_\_\_\_

*vascular tissue*

AATB-accredited OPOs/*tissue banks* \_\_\_\_\_

non-AATB accredited OPOs/*tissue banks* \_\_\_\_\_

health care facilities (e.g., hospital or surgical center) \_\_\_\_\_

**Indicate how many donors of *birth tissue* were provided by the following:**

hospital delivery/birth centers \_\_\_\_\_

freestanding birth centers (not at a hospital) \_\_\_\_\_

AATB-accredited OPOs/*tissue banks* \_\_\_\_\_

non-AATB accredited OPOs/*tissue banks* \_\_\_\_\_

other (specify) \_\_\_\_\_

**Indicate how many donors of *birth tissue* delivered by:**

cesarean section \_\_\_\_\_

vaginally \_\_\_\_\_

**Check here if your *tissue bank* sent any human *tissue* to another *tissue bank* for further manufacture.**

What *tissue* was sent for further manufacture? Check all that apply:

demineralized bone matrix

cancellous bone

bone shafts

other (specify) \_\_\_\_\_

Check here if your *tissue bank processed* any human tissue from non-U.S. sources

List the non-U.S. countries: \_\_\_\_\_

Check here if your *tissue bank imported* human tissue from other countries for *processing and distribution in the U.S.*

List the countries from which donors were imported, the number of donors *processed*, the general types of tissue grafts, and the quantities *distributed*

Country of Origin	No. of donors processed	Types of tissue grafts	Quantity of grafts distributed
_____	_____	_____	_____

(multiple lines)

Check here if your *tissue bank processed tissue* from other countries only for *distribution* by countries other than the U.S. (i.e., *processing contract only*)

Indicate the *tissue received* and the country of origin:

TISSUE FROM DECEASED DONORS

musculoskeletal (i.e., bone, cartilage, osteochondral grafts, osteoarticular grafts):

\_\_\_\_\_

soft tissue (i.e., fascia lata, ligaments, tendons, pericardium, nerves, peritoneal membrane, adipose):

\_\_\_\_\_

*dura mater* \_\_\_\_\_

*cardiac tissue* \_\_\_\_\_

*vascular tissue* \_\_\_\_\_

*skin* \_\_\_\_\_

TISSUE FROM LIVING DONORS

*surgical bone* \_\_\_\_\_

*skin for allogeneic use* \_\_\_\_\_

*autologous bone* \_\_\_\_\_

*birth tissue* \_\_\_\_\_