

Coding and Labelling of Tissues in Europe



Deirdre Fehily



Why are Tissue Coding and Labelling Important?

- Anonymity
- Traceability – global uniqueness
- Standardised product information
- Potential for electronic writing and reading – avoiding transcription errors
- Increases in efficiency

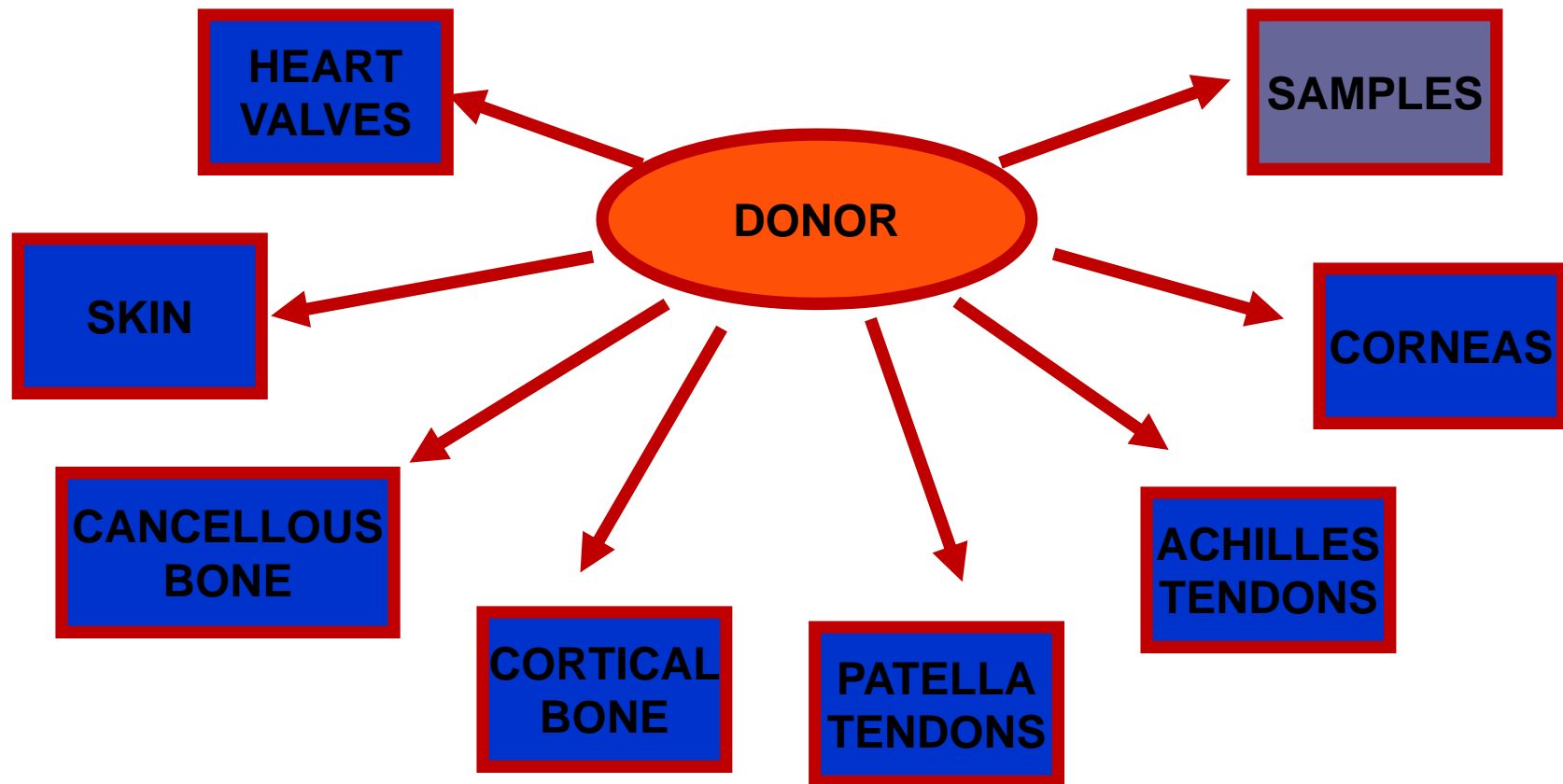


Traceability

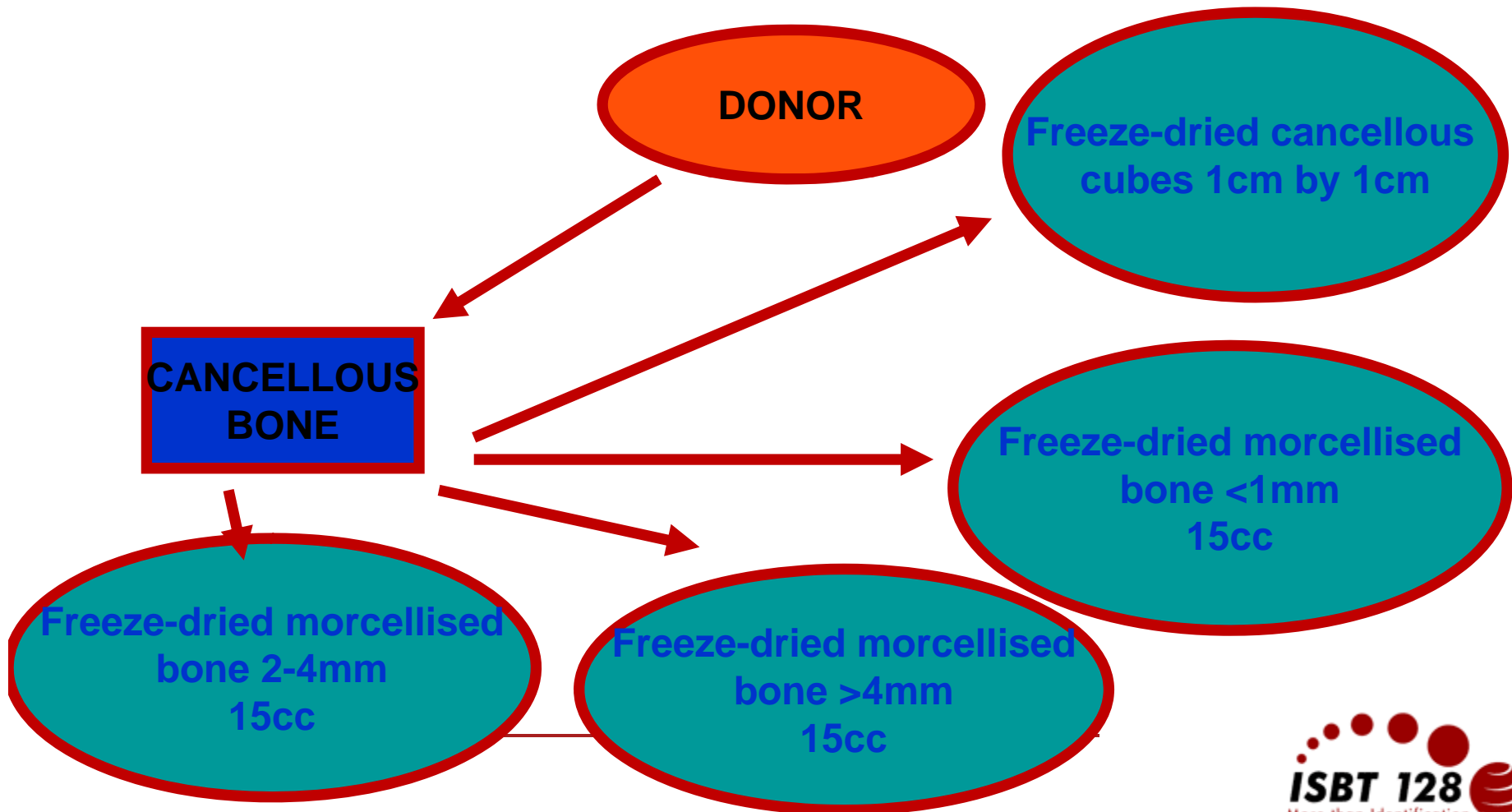
- Donor → Donation → Product → Recipient
- The reverse!
- Secure traceability globally requires global code uniqueness



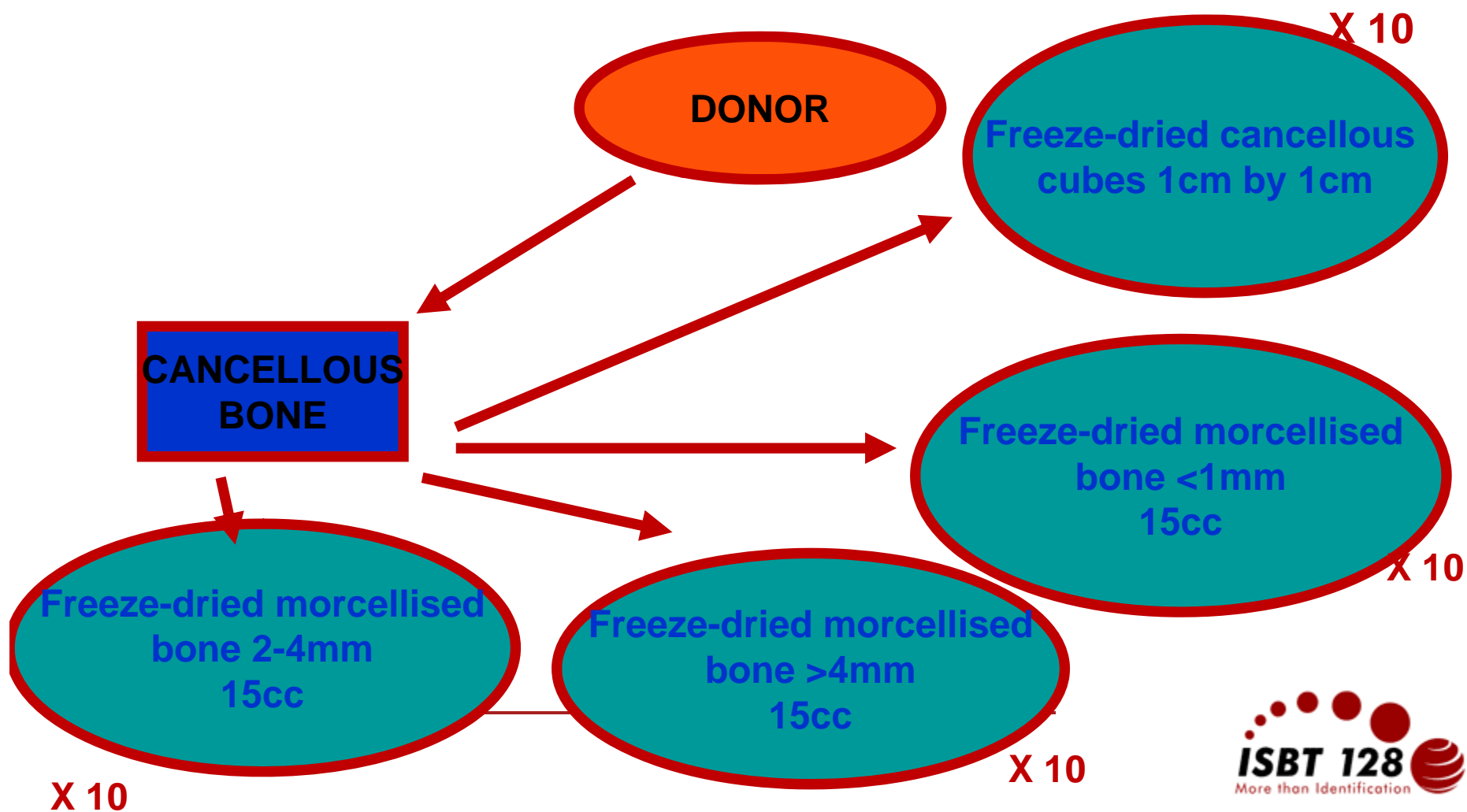
Tissue donation by deceased donors



Complexity of Tissue Processing



Complexity of Tissue Processing



Standardised Product Description

- Must be agreement on the set of words associated with any code
e.g. what does 'freeze-dried sterilized bone' mean?

Cancellous or cortical or both?

Marrow depleted?

Ground? Shaped?

Sterilized how?



MTF Musculoskeletal Transplant Foundation

Human Allograft Tissue

DESCR: ILIAC CREST WEDGE 10-12mm (ACF)

PROD CODE: 100402

DIMEN: T:11mm L:1.8cm W:15mm W2:11mm

SERIAL #: MTF 005592290035 EXP. DATE: 07Jan2010

FREEZE-DRIED Store at Room Temperature. Do not freeze.

Aseptically processed, passes USP <71> for Sterility

Tissue is recovered under aseptic conditions and is aseptically processed. Trace amounts of processing agents may remain. See package insert for these, as well as for contraindications, warnings and preparation for use. FOR SINGLE PATIENT USE ONLY.

125 MAY STREET
EDISON, NJ 08837
(800) 433-6576

Processed by



FlexiGraft™

Donated Human Tissue

Allowash® Tissue Processed
Using Proprietary Technology

Code: FBPL
Graft ID: 06-4026-005

Description:
BISECTED PATELLAR
LIGAMENT (FR)

Size:
I=1.5 TL=5.4 BB=12.6 CM

Exp. Date: OCT 11 2011

Processed with Bacitracin /
Polymyxin B Sulfate
or Gentamicin



R **STERILE**

06-4026-005

FBPL

I=1.5 TL=5.4 BB=12.6 CM
Distributed by LifeNet

06-4026-005

FBPL

I=1.5 TL=5.4 BB=12.6 CM
Distributed by LifeNet

06-4026-005

FBPL

I=1.5 TL=5.4 BB=12.6 CM
Distributed by LifeNet

06-4026-005

FBPL

I=1.5 TL=5.4 BB=12.6 CM
Distributed by LifeNet

06-4026-005

FBPL

I=1.5 TL=5.4 BB=12.6 CM
Distributed by LifeNet

06-4026-005

FBPL

I=1.5 TL=5.4 BB=12.6 CM
Distributed by LifeNet

SINGLE PATIENT USE ONLY
See Package Insert for Handling



LifeNet - 5809 Ward Court - Virginia Beach, VA 23455 - 1-888-847-7831

Electronic reading and writing – avoiding transcription errors



- Donor and donation registration
- Donor testing
- Donation clearance



Benefits of machine-readable labelling in tissue and sample

Significant reduction in the risk of transcription errors in:

- donor identification
- sample and donation identification
- virology/bacteriology result reporting
- final product identification (hence tracking)
- final product description



ISBT 128 for Tissues

- Extended to support Tissue Banking and Cellular Therapy in 2000
- First implementation for tissues was in Europe (NHSBT Tissue Services, UK – full implementation for bone, skin, heart valves, tendons by 2003)
- Currently being implemented in facilities in Poland, Denmark and Austria

ISBT 128 Key Elements



- A donation numbering system that ensures globally unique identification
- Internationally agreed product codes and definitions (blood components, tissues and cells)
- A barcoding system based on code 128
- Applicability to other coding systems (e.g. RFID)

ISBT DONATION NUMERING SYSTEM

G0700 00 123456 8

Source

YR

**Donation
number**

**Check
Digit**

CLASS

The **class** describes the product.
Examples are:

FEMORAL HEAD
CORTICAL BONE RING
AORTIC VALVE
etc.....



MODIFIERS

The **modifier** describes the preservation method and storage state of the component class.

Examples are:

FROZEN

FREEZE DRIED

CRYOPRESERVED

MODIFIER GLOSSARY

FROZEN	Frozen to, and stored at, below –40 C.
CLEANED FROZEN	Processed to remove extraneous tissue and, in the case of bone, to deplete trabecular bone marrow. Frozen to, and stored at, below –40 C.
FREEZE DRIED	Processed to remove extraneous tissue and, in the case of bone, to deplete trabecular bone marrow. Freeze dried to less than 5% residual moisture.
CRYOPRESERVED	Processed to remove extraneous tissue and bacterial and fungal contaminants. Cryopreserved using a cryoprotective agent and stored below –135 C.
DECONTAMINATE D FROZEN	Chemically decontaminated and free of viable bacteria and fungi by culture. Frozen to, and stored at, below –40 C.
GLYCEROLISED	Disinfected and preserved using high concentration (>90%) glycerol. Free of viable bacteria and fungi by culture. Stored at 2-8 C

ATTRIBUTES

A tissue product may be further described through the addition of one attribute value from one or more attribute groups

Some Examples:

Sterilization - indicates the method use to sterilize the product

Unit of Issue - indicates whether the product is supplied as a single unit or a pack of more than one unit

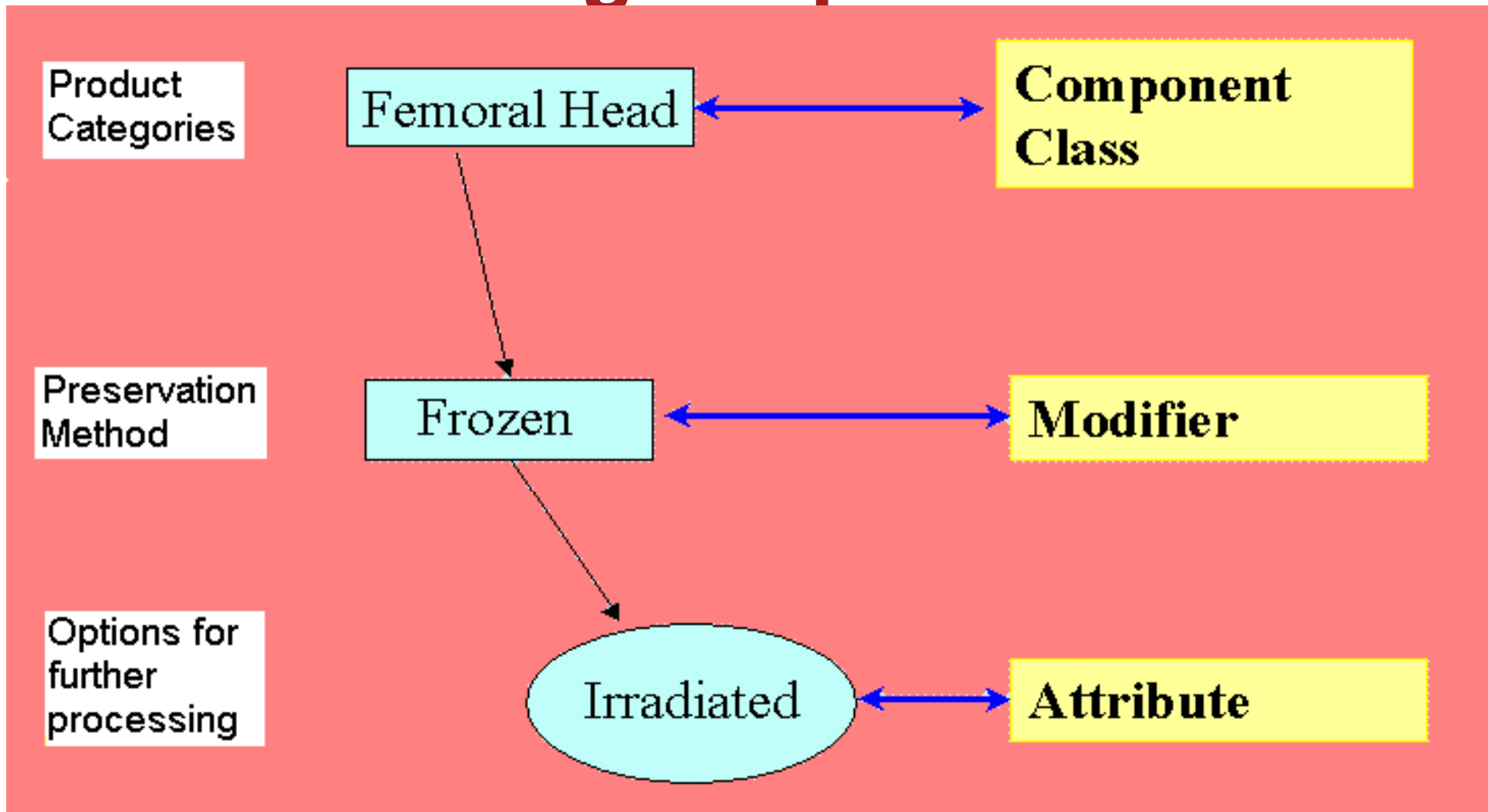
Usage - indicates whether the unit is for direct use or for further manufacture

ATTRIBUTE TABLES

(e.g. granule size)






W1	Default – not defined	
W2	Coarse	$> 4\text{mm and } \leq 6\text{mm}$
W3	Medium	$>2\text{mm and } \leq 4\text{mm}$
W4	Fine	$\leq 2\text{mm}$
W5	Ultrafine	$\leq 1\text{mm}$
W6	Mixed <6mm	$\leq 6\text{mm}$
W7	Mixed <4mm	$\leq 4\text{mm}$
W8	Medium powder	$\geq 1.2\text{mm and } \leq 2.0 \text{ mm}$
W9	Fine powder	$\geq 0.1\text{mm and } < 1.2 \text{ mm}$

Constructing the product code



Product code	COMPONENT CLASS	MODIFIER	Unit of issue	Sterilisation	Granule size
T0001	FEMORAL HEAD	FROZEN	Single		
T0002	FEMORAL HEAD	FROZEN	Single	Terminally Irradiated	
T0003	FEMORAL HEAD	CLEANED FROZEN	Single	Terminally Irradiated	
T0004	FEMORAL HEAD	FREEZE DRIED	Single	ETO sterilised	
T0005	FEMORAL HEAD	FREEZE DRIED	Single	Terminally Irradiated	
T0006	HALF FEMORAL HEAD	FROZEN	Single		
T0007	HALF FEMORAL HEAD	FROZEN	Single	Terminally Irradiated	
T0008	HALF FEMORAL HEAD	CLEANED FROZEN	Single	Terminally Irradiated	
T0009	HALF FEMORAL HEAD	FREEZE DRIED	Single	ETO sterilised	
T0010	HALF FEMORAL HEAD	FREEZE DRIED	Single	Terminally Irradiated	

A standard for tissue labelling using ISBT 128

 W123404123456  Accurate Tissue Bank Anywhere, Worldwide	 T300 FIT FOR CLINICAL USE
 T0027003 FREEZE DRIED GROUND BONE IRRADIATED MEDIUM GRANULE PACK 3 NOMINAL VOLUME: 35 cc	 0041962359 Expiry: 14 JUL 2004 if stored at 20°C or lower See package insert for further details

Directive 2004/23/EC

Article 8:

'Member States shall ensure the implementation of a donor identification system which assigns a unique code to each donation and to each of the products associated with it.'

Article 25

Coding of information

- 1. Member States shall establish a system for the identification of human tissues and cells, in order to ensure the traceability of all human tissues and cells pursuant to Article 8.*
- 2. The Commission, in cooperation with the Member States, shall design a single European coding system to provide information on the main characteristics and properties of tissues and cells.*

But only no one would accept such an awful
crime as it is. It is only longer to walk
in our streets.
If you have any information...



31454 31762



100 100 2

Bansky

European Commission Initiatives

- Sanco Coding Working Group (Official Member State representatives)
- CEN Workshop Process
 - consensus process
 - all interested parties could register
 - chaired by Dr Ruth Warwick, UK
 - three experts employed
- RAND Impact Assessment



Product Codes developed by ICCBA with EU support

EU DG SANCO WG	Country ID + TE	Unique Donation number	Product Code
Variation 1: Globally unique donation, product & "key" codes	Country ID + CA + TE "key code"	Globally unique Donation Code	Globally unique Product Code
Variation 2: National, regional, or local donation code + globally unique product & "key" codes	Country ID + CA + TE "key code"	National, Regional, or Local Donation Code	Globally unique Product Code
Variation 3: National, regional, or local donation & product codes + "key" code	Country ID + CA + TE "key code"	National, Regional, or Local Donation Code	National, Regional, or Local Product Code

Figure 11.2: Proposed EU code structure Variations



ISBT 128 European Tissue Technical Advisory Group



Role of ETTAG (1)

- Develop consensus on detailed implementation of *ISBT 128* tissues in Europe
- Provide a focus for standardization of terminology
- Liaise with EC on coding and labelling issues
- Liaise with other *ISBT 128* Technical Advisory Groups

Role of ETTAG (2)

- Generate, review and comment on proposed changes to the *ISBT 128* Standard
- Advise on future developments of the *ISBT 128* Standard
- Prepare educational material to support implementation of *ISBT 128* for tissues in Europe
- Promote the adoption of *ISBT 128* in Europe and globally

Constitution of ETTAG

- Members from European countries using or implementing *ISBT 128*
- Liaison members from relevant organizations
 - European Commission (?), WHO
- Observers:
 - ☐ Vendors
 - ☐ Competent Authorities who are interested
 - ☐ ESHRE President
 - ☐ Professionals from outside Europe who are interested (Australia, South America, USA)

Progress to date...

- First meeting held during the EATB Conference in Krakow, Poland in November 2009
- Timed to coincide with a WUTCBA meeting (World Union of Tissue & Cell Banking Associations)
- Many WUTCBA observers attended the ET TAG meeting
- WHO represented

Countries/Organisations represented:

- Austria
- Finland
- Sweden
- Norway
- UK
- France (supplier)
- Denmark
- Scotland
- Belgium
- Denmark
- Spain
- Poland
- Argentina
- Brazil
- USA
- Australia
- WHO
- ICCBBA
- AATB, NATTAG
- WMDA

Some key issues discussed in Kracow (1)

- Objectives of ETTAG presented
- Draft Terms of Reference discussed
- Group informed of NATTAG work
- Discussion of coding for Assisted Reproduction field and Advanced Therapy field
- Need for educational support – implementation guidance (important role for Poland)

Some key issues discussed in Kracow (2)

- Code stability (e.g. If there were an EU decision to use a different code)
- Compatibility with hospital software – need for users to inform suppliers of the need
- Delivery mechanisms – need for small labels –presentation of a proposal

Primary Aim of ETTAG: European Consensus Standard



Conference Call meetings

–January, April, May, June 2010

- Discussion proceeded on label design – need for small labels
- Nomenclature – agreed to start work on skin as the product range would not be too wide and it would be a good learning experience for the group

Product Labelling Paper – principles (1)

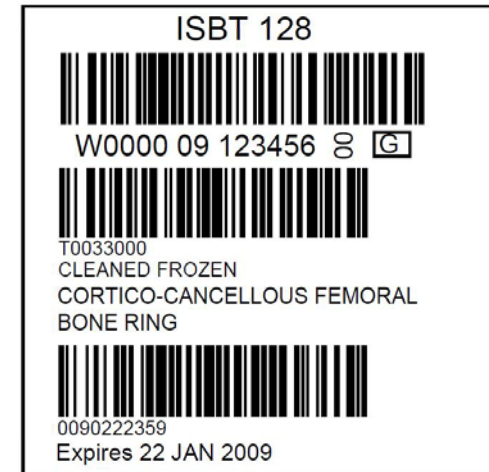
- a unique *ISBT 128* donation identification number must be present in both electronically readable and eye-readable formats on a level of packaging that is opened immediately prior to use;
- a generic product code and name should also be present in both electronically readable and eye-readable formats. Where generic terminology has yet to be finalized, an interim 'bookmark' code can be used that simply identifies the product as a human tissue product;
- the bar codes should carry as a minimum the donation identification number, product code and expiry date. They may also carry collection and/or processing dates, status information and any other relevant *ISBT 128* data structures.

Product Labelling Paper – principles (2)

- The space required for the *ISBT 128* element of labeling could be kept as small as possible consistent with good labeling practice. Tissue Banks could be asked to reserve a small portion of their overall packaging for a common *ISBT 128* element rather than adopt an entirely standard labeling approach;
- 2-dimensional codes (Data Matrix) should be seen as the future direction for coding to allow all machine readable information to be incorporated into a single code in order to reduce space requirements. New equipment should be purchased with this in mind;
- For very small containers, *ISBT 128* labeling of the final product container could be limited to the 2-D barcode only, provided *ISBT 128* eye-readable information is available on a level of packaging that is opened immediate prior to use.
- Three options for small labels presented

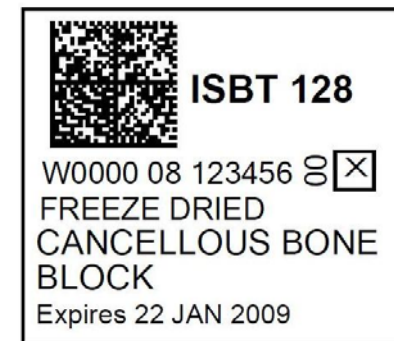
Option 1 – Code 128 – 50 x 50 mm

- The text 'ISBT 128' to identify this as an ISBT 128 label
- An ISBT 128 Donation Identification Number in linear barcode and eye readable format
- An ISBT 128 Product Code in linear barcode and the name of the product (class, modifier) in text
- An ISBT 128 Expiry Date in linear barcode and text format



Option 2 – Data Matrix – ca. 38 x 38 mm

- A 2D (Data Matrix) code containing an ISBT 128 Compound Message (see below)
- The text 'ISBT 128' to identify this as an ISBT 128 label
- The name of the product (class, modifier)
- The donation identification number in eye readable format.
- The Expiry Date in eye-readable format



DIN + product code = 6 mm

DIN + product code+ ABO/Rh + expiry date = 7 mm

DIN + product code+ ABO/Rh + expiry date + 10 character key code = 8 mm

DIN + product code+ expiry date + 10 character key code + dimension data
structure = 10 mm

Option 3 – 2D code only

This would be subject to local regulatory approval, and appropriate mechanisms to verify the code electronically against a full label carried on packaging that is removed immediately prior to use.



Skin Nomenclature (1)

- List of skin product descriptions collated
- Product lists sent by Poland, Sweden, UK, Finland (also Australia and US)
- Cell products also submitted!! (adipocytes, keratinocytes, fibroblasts) – set aside for now
- Work began on the Class and modifier definitions

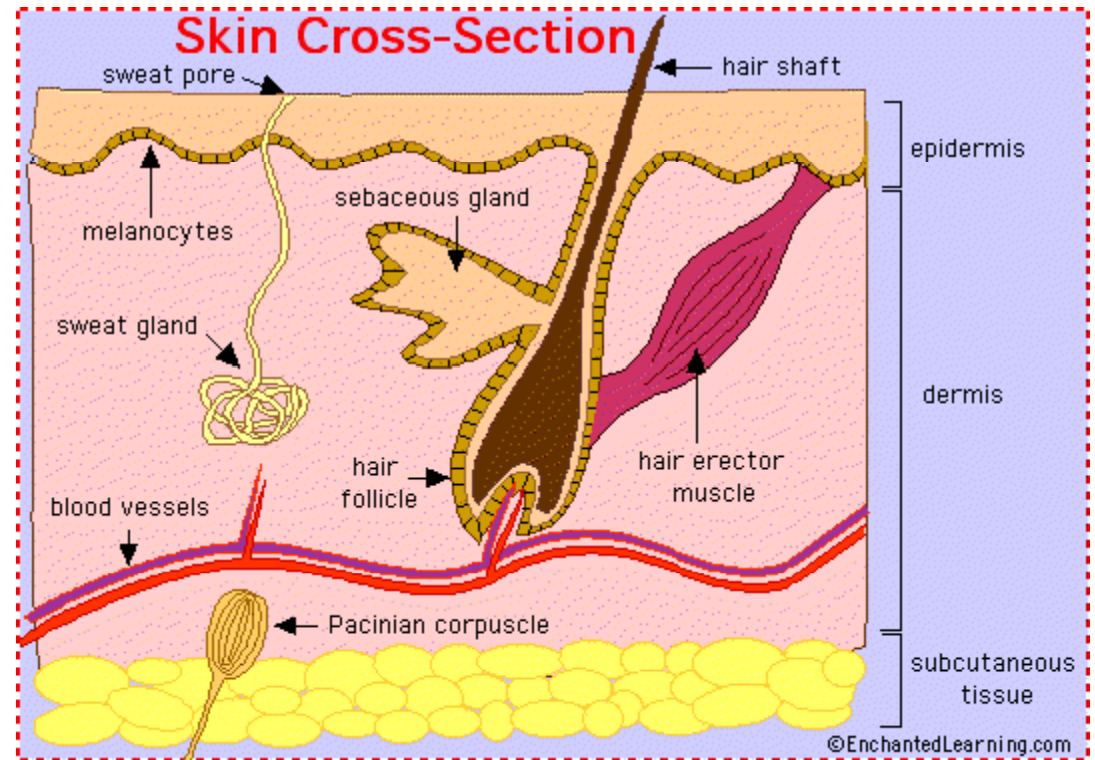
Skin nomenclature – 4 Classes

Skin, Full: Full thickness skin (epidermis and whole dermis)

Skin, Split: Split thickness skin (epidermis and upper part of dermis)

Skin Full with Hypodermis: Full thickness skin with subcutaneous tissue (epidermis, dermis and hypodermis)

Dermis: Skin from which the epidermis and subcutaneous tissue have been removed leaving only the dermal layer.



•Dermis

Copyright ICCBBA

Skin nomenclature - modifiers

1. **Frozen:** Frozen, but not meeting the definition of cryopreservation.
2. **Cryopreserved:** Frozen using a cryoprotective agent and controlled rate cooling.
3. **Freeze Dried:** Lyophilised to remove extraneous moisture by sublimation
4. **Refrigerated:** Refrigerated between 1 and 10°C; national requirements may narrow this range

Skin nomenclature - attributes

- ☐ Usage
- ☐ Cryoprotectant
- ☐ Sterilisation
- ☐ Mesh

Still under discussion....

Moving Forward

- Finalisation of Product Descriptions
- Discussions with Sanco, EU
- Collaboration with WHO