IMPLEMENTATION GUIDE

Use of Product Code [Data Structure 003]

Ocular Tissue

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1 Introduction

1.1 Purpose

The purpose of this document is to provide detailed information about ISBT 128 product coding for ocular tissue. Specifically, it:

- Explains the Product Code Data Structure [003] in detail
- Provides a reference to information about the structure of the Product Description Code (PDC) database
- Explains how to select an appropriate PDC
- Explains how to request new PDCs

1.2 Scope

This document is a supplement to the *ISBT 128 Standard Technical Specification* (ST-001). It provides guidance for eye banks for the use of the Product Code Data Structure [003]. It applies only to ocular products (PDCs that begin with the letter “V”).

1.3 Intended Audience

The intended audience of this document is staff at eye banks (management, information technology, quality, validation, and laboratory), software developers, and vendors of equipment used by eye banks.

1.4 Normative Reference

ISBT 128 Standard Technical Specification (ST-001)

Standard Terminology for Medical Products of Human Origin (ST-002)

ISBT 128 Standard, Labeling of Ocular Tissue (ST-009)

1.5 Other Reference

Implementation Guide: Use of Dimensions Data Structure [029] (IG-026)

1.6 Background

A document entitled *A Specification, ISBT 128*, for labeling blood products was developed by the International Society of Blood Transfusion Working Party on Automation and Data Processing [subsequently renamed the Working Party on Information Technology (WPIT)] and published by ICCBBA in 1995. Originally developed as a coding and labeling standard for blood, ISBT 128 has demonstrated its suitability for use by cell and tissue facilities.

NHS Blood and Transplant in the United Kingdom was the first to consider using a structure based upon the ISBT 128 Product Code model for tissue products. Intended initially as a national code, the proposal was taken forward by ICCBBA as an international standard. Some facilities in other countries (e.g., Poland, Denmark, the Netherlands, and Canada) have since implemented ISBT 128 for tissues.

In 2010, an eye bank professional in Australia expressed interest in using ISBT 128 to code and label ocular tissue. To expand ISBT 128 for ocular tissue, an advisory group, the Eye Bank Technical Advisory Group (EBTAG) was formed with representatives from international eye bank societies, as well as technical and regulatory experts. The societies represented were:

- Association of Eye Banks of Asia
- Eye Bank Association of Australia and New Zealand
- Eye Bank Association of America
- Eye Bank Association of India
- European Eye Bank Association
- Pan-American Association of Eye Banks

EBTAG devised terminology and released it for public comment in 2011. Comments were received and the terminology updated in response to the comments. In August 2012, the terminology was finalized and the Boards of the societies listed above approved the terminology and encouraged their members to utilize ISBT 128. That same month, the first ISBT 128 PDCs for ocular tissue were issued at the request of a Canadian facility. Terminology has been added and modified as additional needs were identified.

EBTAG considered which of the terminology elements should be coded within the ISBT 128 PDC, which could be coded in an alternative data structure within ISBT 128, and which should appear only as eye-readable text. The reasoning behind these decisions was as follows:

Product Description Code: Information will be coded as part of the ISBT 128 PDC when there is a benefit in being able to distinguish distinct types of product through their coding, either to provide electronic support for the management of the supply of product or to categorize products for activity or biovigilance reporting purposes. In addition to coding the information in the PDC data structure, text on the label is required as indicated in Table 1.

Alternative Data Structure: Information may be coded in an alternative ISBT 128 data structure where specific information (such as an exact numerical value) is required that is specific to a particular graft, and when electronic capture of this information by the transplanting organization is desirable. In such cases, a ‘flag’ in the PDC can be used to alert the computer to the presence of this additional electronically-readable information. In addition to coding the information in an alternative data structure, text on the label will be required as indicated in Table 1.

Non-Coded Information: Some information has been identified that does not require coding, but would benefit from standard usage. This is shown in Table 1 (rows where the columns for “Coded in PDC” and “Coded in alternative data structures” columns have “No” but the “Present as text” column has “Optional”). It is discussed in more detail in the

ISBT 128 Standard, Labeling of Ocular Tissue (ST-009). This document is found on the ICCBBA website, www.iccbba.org.

Table 1 Presentation of Information

Information	Coded in Product Description Code	Coded in alternative data structures	Present as text
Class	Yes	No	Yes
Corneal Graft	Yes	No	Yes
Anatomical Position	Yes	No	Yes
Storage State	Yes	No	Yes
Storage Solution	Yes	No	Yes
Endothelial Cell Density (flag)	Yes	No	No
Pathogen Reduction	Yes	No	Yes
Transport Solution	Yes	No	Yes
Portion	Yes	No	Yes
Whole Eye Type	Yes	No	Yes
Lamellar Layer Preparation	Yes	No	Yes
Ocular Tissue, Non-Clinical	Yes	No	Yes
Endothelial Cell Density (value)	No	Optional	Optional
Additional Consent	No	No	Optional
Additional Donor Information	No	No	Optional
Corneal thickness	No	Optional	Optional
Corneoscleral disc diameter	No	No	Optional

1.7 Changes in this Version

The following table indicates the major changes between Version 1.1.0 and Version 1.2.0. Actual changes or additions to requirements of the ISBT 128 Standard are in bold print; changes to formatting or organization, or additional guidance, are in regular print.

If changes were a result of a formal proposal, the number of the proposal is listed in the Rationale column.

	Version 1.1.0	Version 1.2.0	Change	Rationale
1.	Throughout	Throughout	The name of the document *Standard Terminology for Blood, Cellular Therapy, and Tissue Product Descriptions w*as changed to *Standard Terminology for Medical Products of Human Origin* (ST-002)	This title better describes the range of products that can be labeled using ISBT 128.
2.	Throughout	Throughout	Updated the document to include current Attribute groups and variables.	Attribute groups and variables have been added and retired.
3.	New information	3.1.2	Provided information about the order in which Attribute variables should appear.	This was done to place the Attribute variables in a logical sequence on the label.
4.	3.1.3	Removed	Information about the changes to the structure of the database were removed.	The reader was referred to *ISBT 128 Standard Product Description Code Database* (ST-010) that contains this information.
5.	**4**	**4**	**Changed the wording from "shall" to "should" in the sentence: When a product is not divided, or where the division number does not need to be specifically identified, the product division characters should be set to "000" (three zeroes).**	**While it is recommended that 000 be used when the product is not divided, this is not required.**

2 Product Code [Data Structure 003]

Purpose: Data Structure [003] shall identify a product intended for human use according to the ISBT 128 scheme of Class, Modifier, and Attribute(s) and to encode information about whether or not the product has been divided. (*Note: Modifiers are not used for ocular tissue. Only Classes and Attributes are used.)*

Structure: =<αooootds.

Element	Length	Type
=	1	data identifier, first character
<	1	data identifier, second character
α	1	alphabetic {A–Z} See below
oooo	4	numeric {0–9}
t	1	alphanumeric {A–Z; a–z; 0–9} (Depends on value of α, see below)
d	1	alphanumeric {A–Z; 0–9}, (Depends on value of α, see below)
s	1	alphanumeric {a–z; 0–9} (Depends on value of α, see below)

The eight (8)-character data content string, **αooootds** shall be encoded and interpreted as follows.

αoooo shall specify the PDC and shall be encoded and interpreted by reference to the PDC database table published and maintained by ICCBBA in the password-protected area of the ICCBBA Website.

α shall specify the following product categories.

- V will represent Ocular tissue.
- A-D – national or local codes (see section 3.2).

Other **α** are defined in the *ISBT 128 Standard Technical Specification* (ST-001).

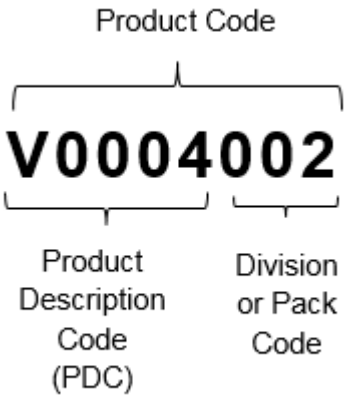
oooo shall be interpreted through reference to the PDC database

tds The encoding and interpretation of **tds** shall depend upon the value of **α**. If **α** is V, **tds** shall specify a 3-digit number of divisions/packs of the product. These three characters provide a means to uniquely identify multiple occurrences of ocular tissue products identified with the same PDC and derived from the same donation event. See chapter 4 for examples. If multiple divisions/packs do not exist, **tds** shall be set to 000 (three zeroes).

If **α** is A-D, tds is not defined. If tds is set to something other than 000, it shall be defined in conjunction with the national/local code assignment.

Thus, the full Product Code is eight characters long, with a five-character PDC and a three-character division/pack code as shown in Figure 1.

Figure 1 Product Code



3 Product Description Codes (PDCs)

3.1 Internationally Standardized PDCs

The first five characters of the Product Code map to a standardized description of the ocular tissue product in the PDC database. The products are described through the use of Class and Attributes. Each of the characteristics that make up the product description is defined in the document: *Standard Terminology for Medical Products of Human Origin* (ST-002).

In general, the descriptions included in the ISBT 128 database tables are intended for use in final product labeling. A “final product” is defined as a product appropriate for transfer from the recovery and/or processing facility inventory to some other inventory. However, facilities may optionally use ISBT 128 Product Codes internally from the time of the recovery of the ocular tissue.

An outdate period is not defined in the description since each country determines the permissible period after recovery or further processing during which the ocular tissue product may be used.

The PDC does contain information about manufacturing, but is not intended to be a complete record of all processing steps; that is, it is not a portable data file of the manufacturing process.

3.1.1 Terminology

The PDC uniquely defines an ocular tissue product in terms of its characteristics. All products have a Class; products may also have one or more Attributes.

3.1.1.1 Class

Class is a general description of ocular tissue products (such as Cornea or Sclera).

3.1.1.2 Attributes

Attributes provide additional information about the ocular tissue product. Ocular tissues thus may be further described through the addition of one Attribute variable from one or more Attribute groups.

Ocular tissue Attributes are organized into groups:

- Corneal Graft: Specifies the type of corneal graft.
- Anatomical Position: Describes the relative position of the tissue in the donor’s body prior to tissue procurement.
- Storage State: Specifies the storage state of the tissue in the eye bank. Delivery conditions may vary.

- Storage Solution: Specifies the solution in which the tissue is stored in the eye bank.
- Endothelial Cell Density: An indicator of whether the endothelial cell density is included in the labeling.
- Pathogen Reduction: Describes the method of sterilization, disinfection, or decontamination of the product.
- Transport Solution: Specifies the solution in which the tissue is transported from the eye bank.
- Portion: Describes the portion of the ocular tissue.
- Whole Eye Type: Specifies types of Whole Eye.
- Lamellar Layer: Preparation: Describes the method used to prepare the corneal lamellar layer(s).
- Type of Non-Clinical Tissue: Describes source of tissue that is not to be used for patient treatment/transplant either directly or as a starting material for regenerative medicine.

Attribute groups have default values:

For the purposes of these ocular product descriptions, unless otherwise stated, it is assumed that the “default” state applies. The default state specifies that:

- Corneal Graft default: Either this Attribute group does not apply (tissue Class is not Cornea) or the corneal graft type is not specified.
- Anatomical Position default: No information is provided as to the relative position of the tissue in the donor’s body prior to tissue procurement.
- Storage State default: No coded information about storage state is provided. Details may appear in text on the tissue container label or in accompanying documentation.
- Storage Solution default: No coded information about the storage solution is provided. Details about the storage solution may appear as text on the tissue container label or in accompanying documentation.
- Endothelial Cell Density default: No information about the endothelial cell density is provided.
- Pathogen Reduction default: No information about pathogen reduction is provided.
- Transport Solution default: No transport solution is specified in the coding.
- Portion: Information not specified in the coding. May be specified in accompanying documentation.
- Whole Eye Type: Either this Attribute group does not apply (tissue Class is not Whole Eye) or the type of Whole Eye is not specified.
- Lamellar Layer Preparation: The method of preparation of lamellar layer(s) is not specified or this Attribute group does not apply. The Attribute group would not apply either because the tissue is not cornea or because the cornea is a full-

thickness cornea that has not been divided into lamellar layers.
- Type of Non-Clinical Tissue: Either the tissue is for clinical use or, if for non-clinical use, the type of non-clinical tissue is not encoded.

The document *Standard Terminology for Medical Products of Human Origin* (ST-002) provides complete descriptions of currently defined ocular tissue Classes and Attributes.

3.1.2 Structure of Product Descriptions within the Database

Once defined, product descriptions are placed into a reference table database. Each description is assigned a unique five-character PDC for electronic communication. Although there is no structure to the five-character PDC, the description of the product within the database is rigidly structured. Each product is defined in the ICCBBA database minimally in terms of its Class.

The Class and Attributes are separated in the product name by the "|" delimiter: CLASS|Attribute

For example:

Product Description Code	Description
V0003	CORNEA|Right|Hypothermic storage

Attributes are used to further describe the product. One variable from each group may be selected. The order in which the Attributes appear in the description field of the database is:

- Corneal Graft
- Anatomical Position
- Storage State
- Storage Solution
- Endothelial Cell Density
- Pathogen Reduction
- Transport Solution
- Portion
- Whole Eye Type
- Lamellar Layer Preparation
- Type of Non-Clinical Tissue

If an Attribute variable (other than the default value) from one of the Attribute groups shown in Table 2 is used, text for this variable should appear in the order shown in the table. Other Attributes should appear in a nationally-defined order following Attributes from the groups listed in Table 2, or, if there is not a nationally-defined order, in the order determined by the facility. Ideally, software should be developed to allow users to configure the order in which attributes will appear.

Table 2 Order of Attribute Text on Labels

Attribute Group	Location on Label
Corneal Graft	Immediately beneath the Class name “CORNEA”.
Whole Eye Type	Immediately below the Class “WHOLE EYE”.
Lamellar Layer Preparation	Immediately below the Corneal Graft Type Attribute.
Portion	For Cornea: • Immediately below the Lamellar Preparation Attribute, if present. • If the Lamellar Preparation Attribute is not present, immediately below the Corneal graft Attribute. For Sclera: Immediately below the Class name “SCLERA”.
Type of Non-Clinical Tissue	Immediately beneath the Class name “OCULAR TISSUE, NON-CLINICAL”.

3.1.3 Structure of Database

Details of the database structure are found in *ISBT 128 Standard Product Description Code Database* (ST-010).

All ISBT 128 database tables shall be published in the password-protected area of the ICCBBA Website. This file is a Microsoft Access® file and is listed on the Website as:

ISBT 128 Product Description Code Database

3.1.4 Selecting PDCs from Existing Codes

Ocular PDCs begin with the letter “V”. The codes are listed in alphabetical order in the full database so ocular codes are found near the end of the full database table.

To appropriately select product descriptions, it is important to understand the definitions of each term. These definitions are found in *Standard Terminology for Medical Products of Human Origin* (ST-002).

3.1.4.1 “Retired” Codes

Over time, codes may become inappropriate, redundant, or errors may be discovered. As a result, a mechanism must exist to

discontinue future use of these codes. However, because products may exist in inventories across the world, the codes must be retained in the database for backward compatibility.

To accomplish this goal, a column exists in the ICCBBA database to indicate such codes. This “Retired Date” column indicates the date on which ICCBBA recommended the codes no longer be used for new products. Therefore, codes with a date in the “Retired” field should not be selected for labeling of new products.

Software should be written to recognize these codes, but not assign them to newly created products.

It is understood that facilities must be given time to retire codes after ICCBBA has made its recommendation.

3.1.4.2 Level of Detail

Following national guidelines, facilities can determine the level of detail that must be encoded into an electronically-readable format according to the needs of its customers. For example, a facility may choose to use a product description that includes just a Class (e.g., Cornea). Or, they may select a product description that includes Attributes describing the product: A cornea with anterior and posterior layers from the left eye and preserved by hypothermic storage.

3.1.4.3 Finding PDCs

Queries

Currently, there are not very many PDCs for ocular tissue. Therefore, a query can be used to review all ocular codes to select the best one.

A query is available within the PDC database that can assist the user by focusing on only the information needed. This query is called: Ocular Codes.

Lookup Tool

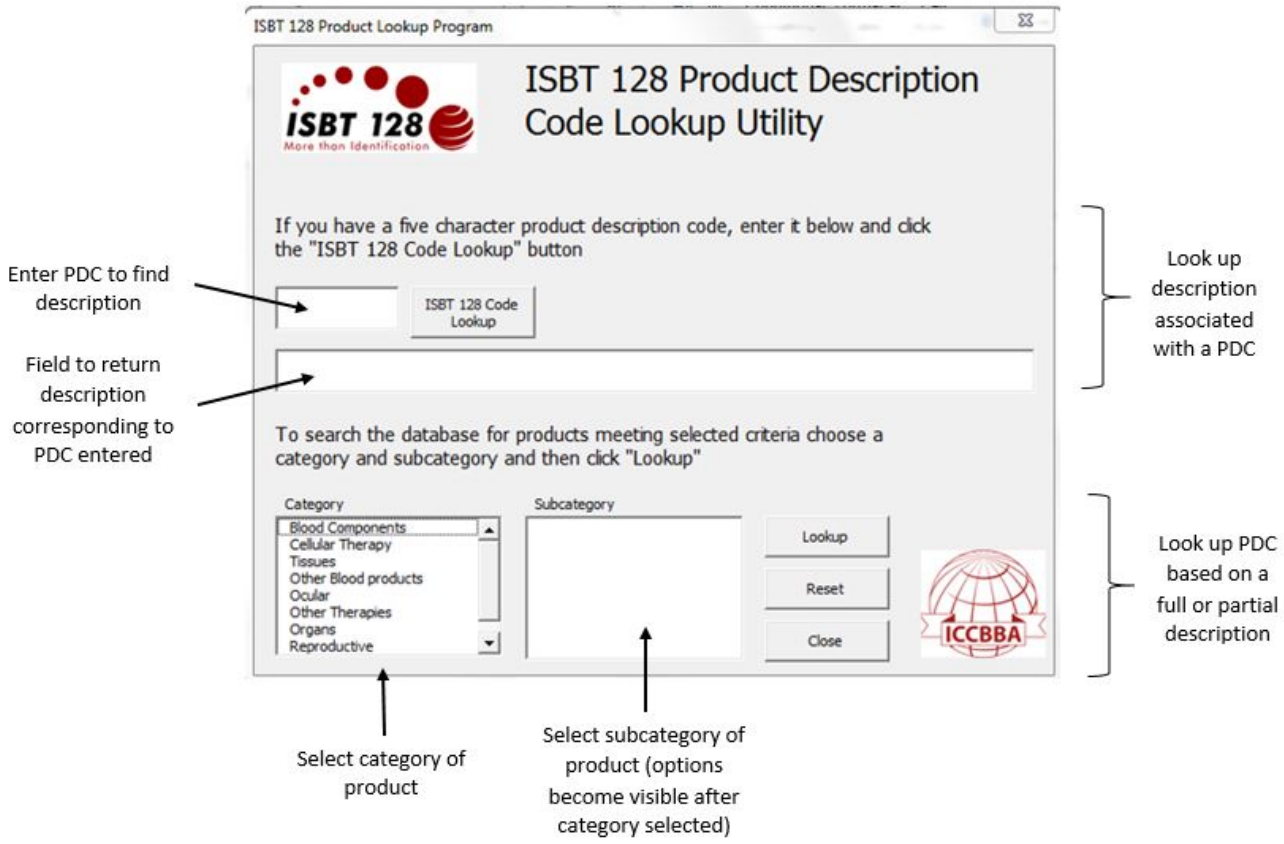
Searching for the correct PDC can be simplified by the use of the PDC lookup tool available on the ICCBBA Website. (From home page, select “Lookup Tools” from the menu at the top of the page. Then select “Find Product Information.”) This is a Microsoft Excel file that can be downloaded onto your computer. It is compatible with Microsoft Excel 2007-2013. It has not been validated, and should not be used, with earlier versions of Microsoft Excel.

It is updated with each new version of the PDC database (approximately once a month). Therefore, users must download this tool frequently to ensure the most recent PDCs are available.

The program can be used to lookup a description for a given PDC or lookup a PDC based on a description.

When the program is opened, the ISBT 128 Product Description Code Lookup Utility screen will appear. See Figure 2.

Figure 2 Opening Screen



To find the description when you know the PDC. See Figure 3.

- Enter the PDC in the first field.
- Click on the ISBT 128 Code Lookup button.
- The description will appear in the field below the ISBT 128 Code Lookup button.
- To lookup another description, click the Reset button and repeat the first 3 steps.
- To close tool, click the Close button.

To find a PDC for a given product description:

- Click on Ocular in the Category Field and Ocular in the Subcategory field. See Figure 4. (Currently, category and subcategory are the same, but this will not always be the case.)
- Click the “Lookup Button” to the right of the Subcategory field.
- The ISBT 128 Product Lookup by Description screen will appear. See Figure 5.
- Click on the Class desired. See Figure 5.
- Select Attributes, if desired. See Figure 6.
    - Click on the Attribute Group desired. Attribute values corresponding to the Class selected will appear in the Attribute Value field.

    - Click on the value desired. This value will appear in the Selected Attributes window.
    - Select additional Attributes following these same steps.
- At this point there are two options, “Exact Match” and “Find.”
    - Clicking “Exact Match” will bring up the PDC that exactly meets the selection criteria. See Figure 7.
    - Clicking “Find” will result in a list of products that include these criteria. See Figure 8.
- If desired, click the Export List button to export the list of products in a text file to a selected location. See Figure 9 and Figure 10. The text file will be named Product Description Codes. (Note: If you export a second list to the same location, it will overwrite the first list unless you change the name of the file.)
- Use the Reset button to clear the screen and allow a new query to be performed.
- Use the Close button to close the tool.

Figure 3 Looking Up a Description Using the PDC

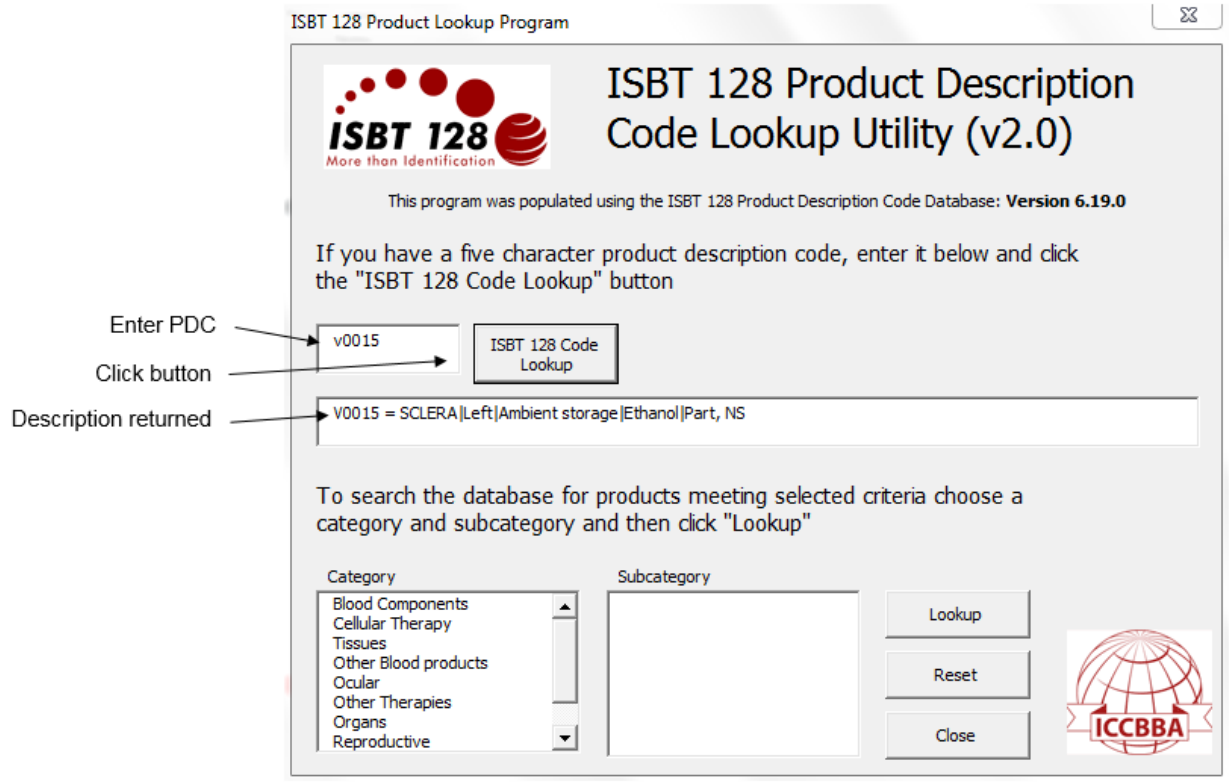


Figure 4 Looking Up a PDC from a Description (Opening Screen)

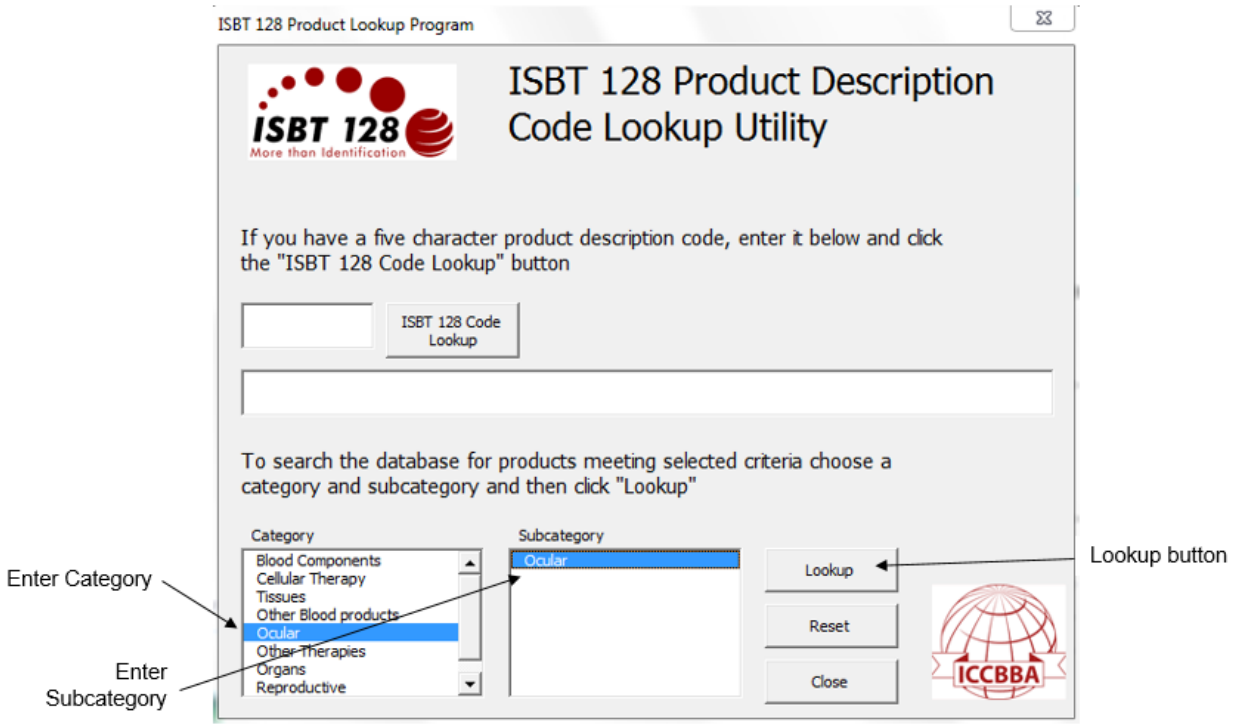


Figure 5 ISBT 128 Product Lookup by Description Screen.

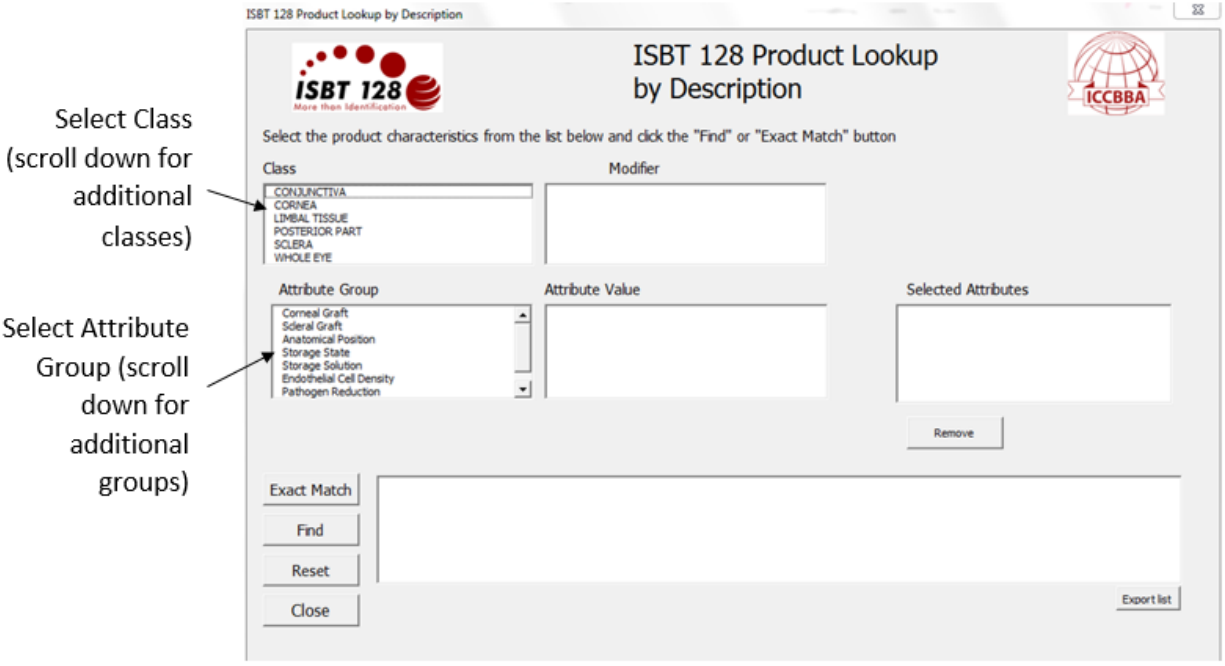


Figure 6 Describing Product

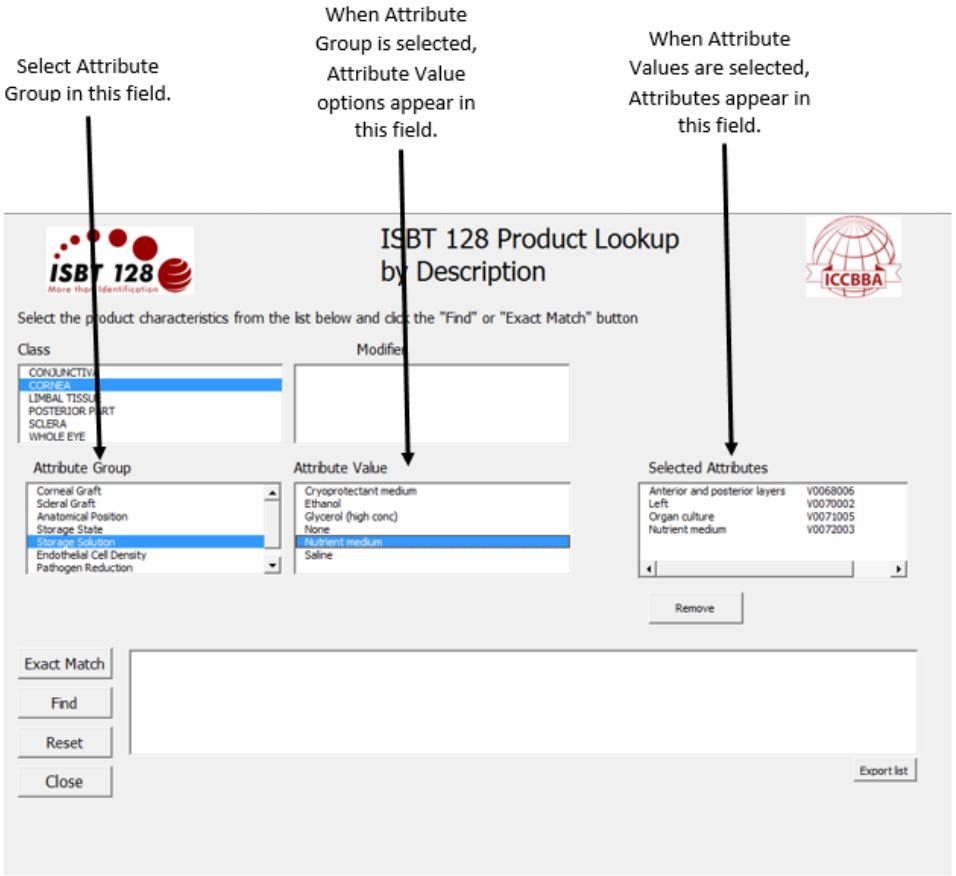


Figure 7 Lookup PDC that Exactly Matches Criteria

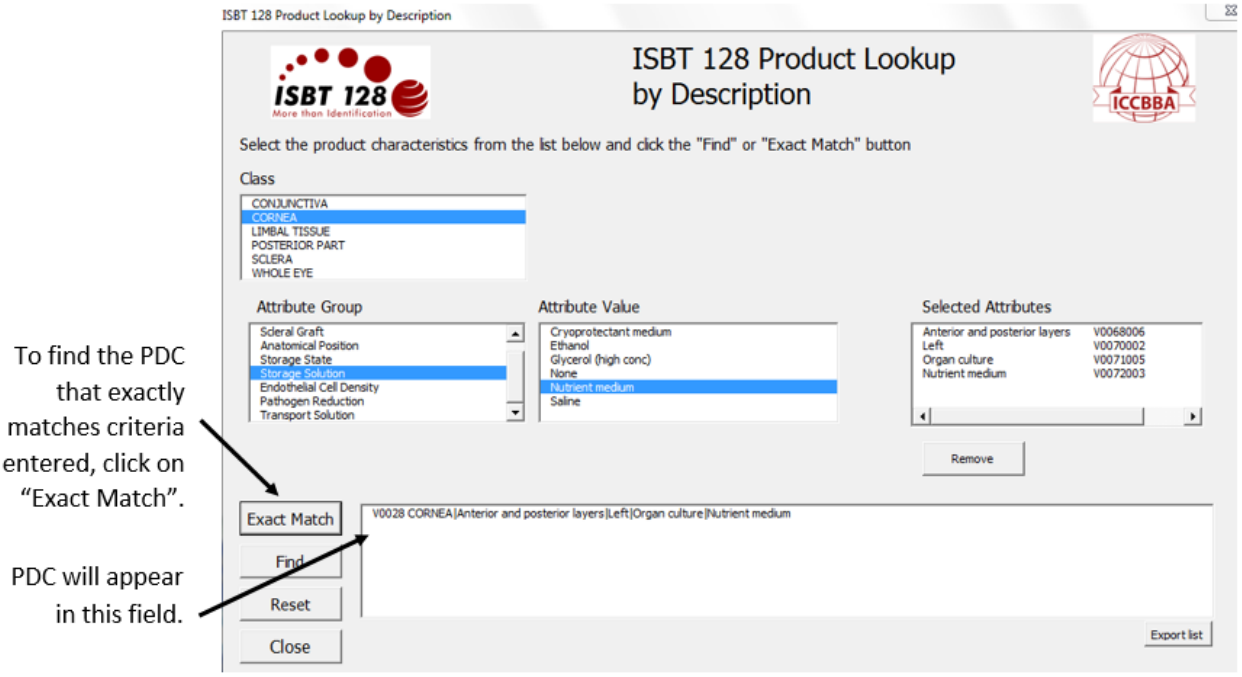


Figure 8 Lookup All PDCs that Meet Criteria

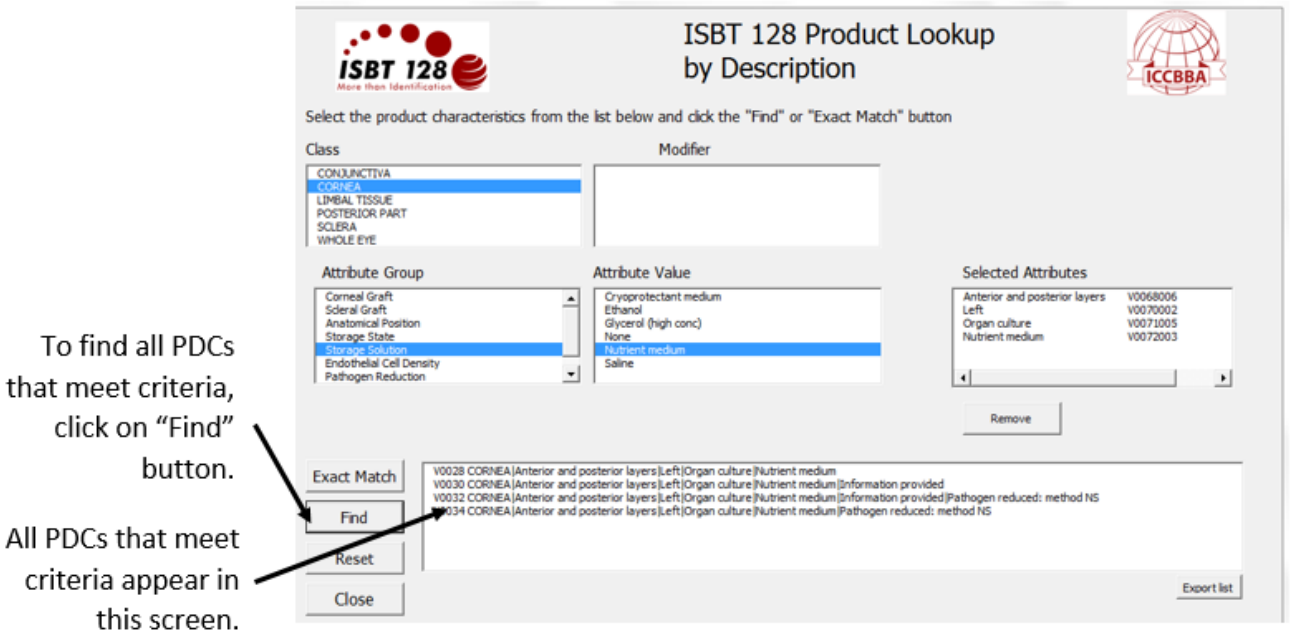


Figure 9 Use of Export List Function

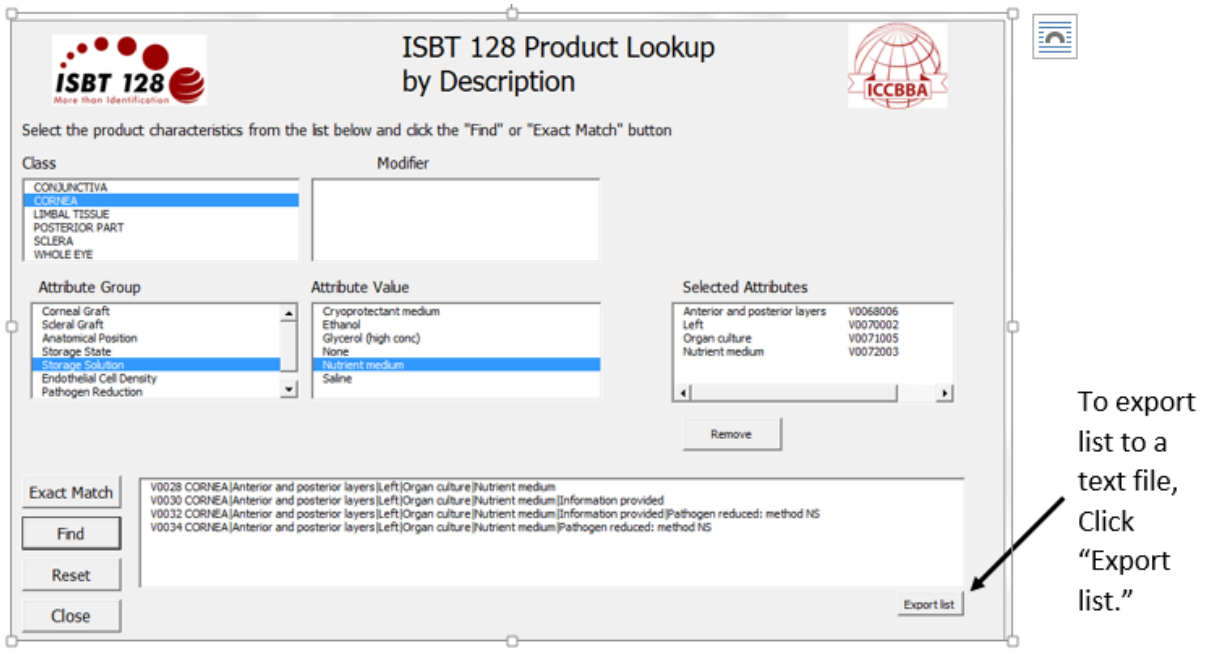
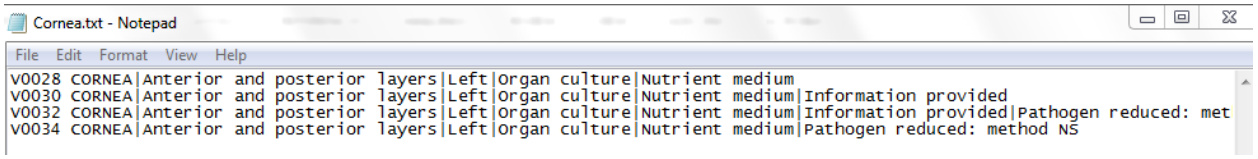


Figure 10 Text File Created by Lookup Tool



3.1.5 Requesting New PDCs

If the code needed does not exist, a new code may be requested. An on-line form for requesting a new PDC for ocular tissue is available on the ICCBBA Website. See Figure 11. Instructions for completing it are found in Section 3.1.5.1.

Countries are encouraged to appoint an individual or committee to manage code requests on a national basis in order to retain consistency within the country.

Codes that represent new combinations of existing Classes or Attributes will generally be added on the next database update. The database is updated approximately 10 times each year. Codes requiring new terminology will take longer.

Updates to the PDCs will be regularly posted in the password protected section of the ICCBBA Website and made apparent by a change in the Version Number of the ISBT 128 Product Description Code Database. A version control sheet describing the changes is published with each update. Users may subscribe to a service allowing them to be notified of updates to the database by email. Access to this subscription service is found on the home page of the ICCBBA Website.

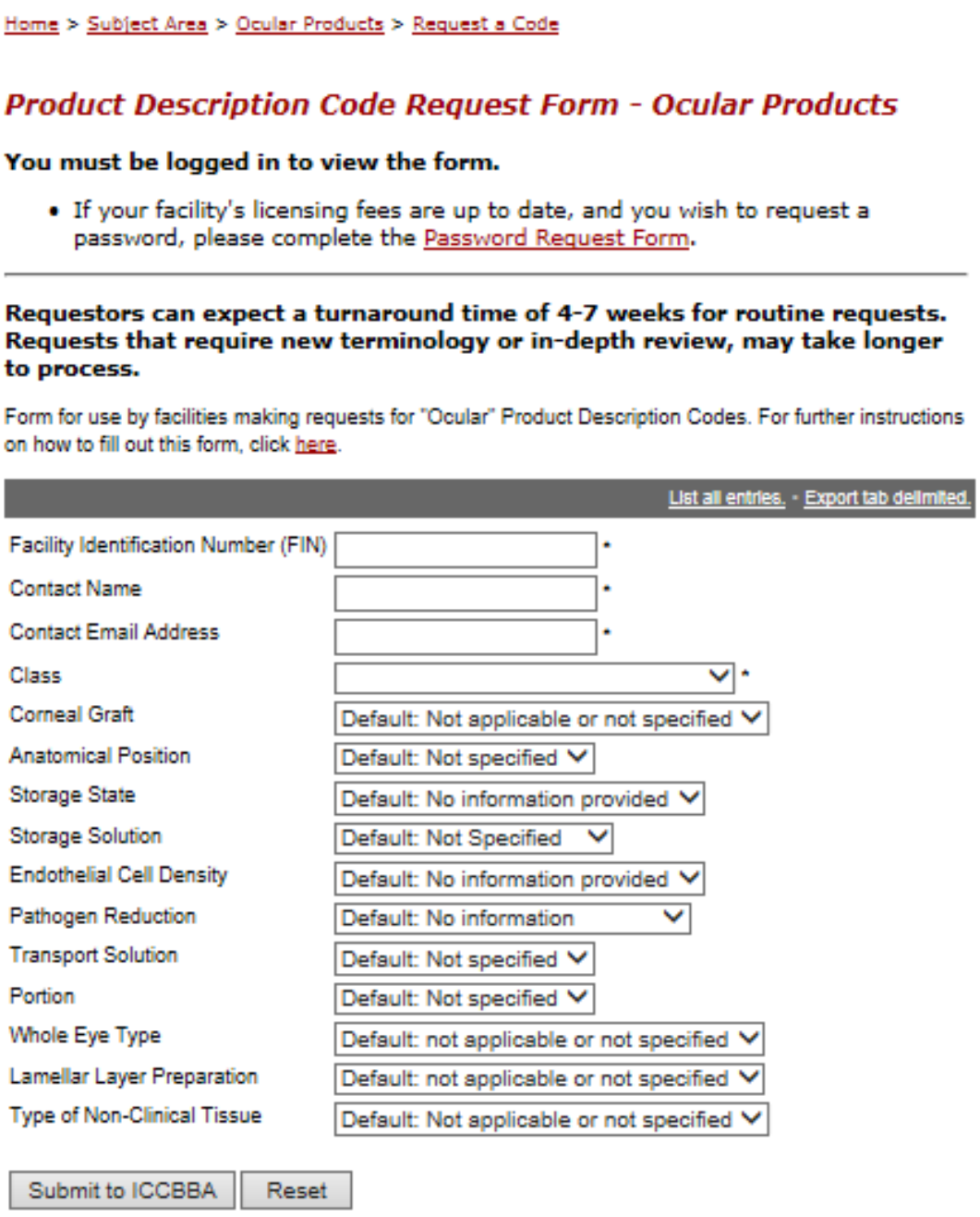
3.1.5.1 Completing and Submitting the Request Form

The form for requesting new ocular tissue codes is found on the ICCBBA Website. It is found in the Subject Area tab, under Ocular Products and is called Request a Code. One completed form is required for each new PDC requested. See Figure 11.

- Minimally, the request must include a Class. Select one Class from the dropdown list. See Figure 12.
- Select an Attribute from each Attribute group where a non-default value is required (only one per Attribute group) from the dropdown lists.
- Click on the “Submit to ICCBBA” button to submit the form to the appropriate individual at ICCBBA. You will receive an automated acknowledgement of the submission. Questions should be submitted to ICCBBA at iccbba@iccbba.org.

ICCBBA staff will contact you during the process of coding the requested product and when the code is published.

Figure 11 On-Line Request Form



Home > Subject Area > Ocular Products > Request a Code

Product Description Code Request Form - Ocular Products

You must be logged in to view the form.

- If your facility's licensing fees are up to date, and you wish to request a password, please complete the Password Request Form.

Requestors can expect a turnaround time of 4-7 weeks for routine requests. Requests that require new terminology or in-depth review, may take longer to process.

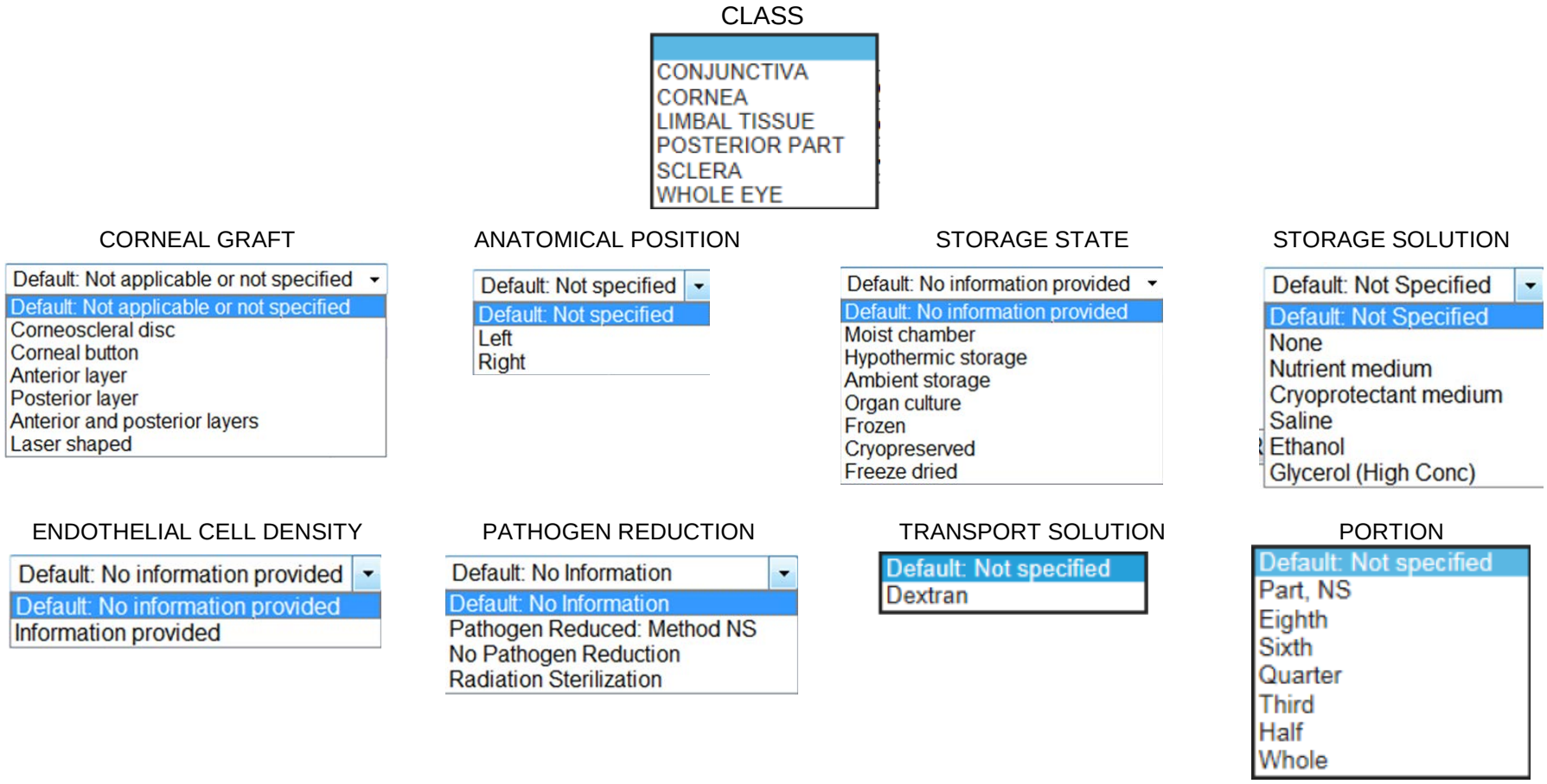
Form for use by facilities making requests for "Ocular" Product Description Codes. For further instructions on how to fill out this form, click here.

List all entries. - Export tab delimited.

Facility Identification Number (FIN)	*
Contact Name	*
Contact Email Address	*
Class	*
Corneal Graft	Default: Not applicable or not specified
Anatomical Position	Default: Not specified
Storage State	Default: No information provided
Storage Solution	Default: Not Specified
Endothelial Cell Density	Default: No information provided
Pathogen Reduction	Default: No information
Transport Solution	Default: Not specified
Portion	Default: Not specified
Whole Eye Type	Default: not applicable or not specified
Lamellar Layer Preparation	Default: not applicable or not specified
Type of Non-Clinical Tissue	Default: Not applicable or not specified

Submit to ICCBBA Reset

Figure 12 Examples of Drop-Down Menus



WHOLE EYE TYPE

Default: not applicable or not specified
Contents removed

LAMELLAR LAYER PREPARATION

Default: not applicable or not specified
Laser
Manual dissection
Microkeratome

TYPE OF NON-CLINICAL TISSUE

Default: Not applicable or not specified
Cornea
Iris
Lens
Optic nerve
Posterior part
Retina

3.1.5.2 Requesting New Terminology

If a new Class, Attribute group, or variable within an Attribute group is needed, please contact the ICCBBA office (iccbba@iccbba.org). A definition compatible with the format of those in the *Standard Terminology for Medical Products of Human Origin* should accompany such a request. Requests for new terminology will be reviewed by the Eye Bank Technical Advisory Group to ensure international consensus.

New terminology must be compatible with the existing system. If there is a question of compatibility, the request may be referred to the Standards Committee of ICCBBA.

3.2 Product Codes Designated for Local or National Use

The block of PDCs, A0000-D9999, has been reserved for use as nationally- or facility-defined product codes. There will be no international interpretation associated with these values. Because this range of values is used by all categories of products (blood, cellular therapy, tissue, etc.), use of these codes for products that are shipped outside the facility should be coordinated with other organizations.

These codes should ONLY be used where there is not an appropriate international code and there is good reason why an international code should not be allocated. Local codes should be used when a product is only produced in one or a very small number of facilities. If there is any uncertainty whether the code assigned to a product should be international or local/national, the user should contact the ICCBBA office.

National agencies may elect to reserve a range of these values for national assignment. Where this is done it is the responsibility of the national agency to ensure that definitions are provided for use within the country and that products bearing such codes are not transferred outside the national boundary.

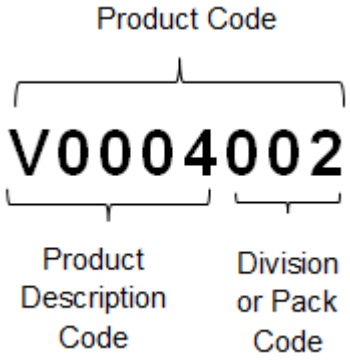
Individual facilities may also assign codes for their own use provided that these do not conflict with codes assigned at the national level. Where such codes are used, it is the responsibility of the facility to ensure that definitions are provided for use within their service region, and that products bearing such codes are not transferred outside their normal distribution network. Care should be taken in interpreting the product description from a local code as this will be specific to the supplier.

In all cases, the product definition for nationally- or facility-assigned codes must be retained permanently for traceability purposes. Once assigned, codes should not be reassigned.

4 Division or Pack Codes

The purpose of the product division or pack code (last 3 characters of the Product Code) is to provide a means to uniquely identify multiple occurrences of ocular tissue products identified with the same PDC and derived from the same donation event.

Figure 13 Product Code



Where multiple identical products result from a single donation, individual divisions are distinguished by these characters. For example:

V0007001 Container 001 of SCLERA|Right|Hypothermic storage|Part, NS
V0007002 Container 002 of SCLERA|Right|Hypothermic storage|Part, NS

V0008001 Container 001 of SCLERA|Left|Hypothermic storage|Part, NS
V0008002 Container 002 of SCLERA|Left|Hypothermic storage|Part, NS

When a product is not divided, or when the division number does not need to be specifically identified, the product division characters should be set to “000” (three zeroes).

5 Questions?

If you have additional questions about product coding, or the selection of the appropriate PDC for your products, please contact the ICCBBA office (iccbba@iccbba.org).

