



Technical Bulletin

Revised Reproductive Terminology

Version 1.0.0

January 2020

Tracking Number ICCBBA TB-014



Published by:
ICCBBA

PO Box 11309, San Bernardino, CA 92423-1309 USA

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1 Introduction

1.1 Purpose

The purpose of this document is to provide guidance to users on the changes made to the Reproductive Terminology in version 7.32 of the *ISBT 128 Standard Terminology for Medical Products of Human Origin* (ST-002).

1.2 Scope

This document is a supplement to the *ISBT 128 Standard Terminology for Medical Products of Human Origin* (ST-002) and specifically addresses the changes to the Reproductive Terminology implemented in version 7.32.

This document will not be updated as new Reproductive Terminology is added.

1.3 Intended Audience

The intended audience of this document is staff at Assisted Reproductive Technology (ART) facilities, hospitals that receive ART products (managers, information technology, quality, validation, and laboratory), software developers, and label/software vendors.

1.4 Normative References

ISBT 128 Standard Terminology for Medical Products of Human Origin (ST-002)

1.5 Other References

ICCBBA website (www.iccbba.org)

Ashford P, Rydman K, Sparks A, Tilleman K, Freire M. Standard terminology for reproductive tissue and cell products for use in ART. *Hum Reprod Open* 2019;2019(2). <https://doi.org/10.1093/hropen/hoz005>.

Zegers-Hochschild F, Adamson GD, Dyer S, et al. The International Glossary on Infertility and Fertility Care, 2017. *Hum Reprod* 2017;32(9):1786-1801. <https://doi.org/10.1093/humrep/dex234>.

1.6 Background

ICCBBA established a working group in 2016 to review the initial terminology for ART products. In early 2017, representatives from the American Society for Reproductive Medicine (ASRM), the European Society of Human Reproduction and Embryology (ESHRE), and the Reproductive Tissue Council of the American Association of Tissue Banks joined the group and the Assisted Reproductive Technology Technical Advisory Group (ARTTAG) was formed to continue the development of the terminology.

The ARTTAG reviewed the existing terminology and released a revised draft for public consultation in August 2017. Comments were received from several sources and these were used to further refine the terminology. In particular, modifications were made to align the terminology with “The International Glossary on Infertility and Fertility Care, 2017” (Zegers-Hochschild et al. 2017).

In March 2019, the revised terminology was announced in the article “Standard terminology for reproductive tissue and cell products for use in ART” (Ashford et al. 2019) published in the journal Human Reproduction Open of the European Society of Human Reproduction and Embryology.

The changes to the existing Reproductive Terminology are found in the following sections of this document:

- Classes
- Attributes
- Product Description Codes (PDCs)

In some cases, the changes made to the terminology resulted in PDCs to be renamed, created, or retired.

2 Classes

Some existing class definitions were revised and a new class was created as a result of the changes to the terminology. See Table 1.

The new definition of EMBRYO is not fully backward compatible with the old definition because it excludes “fertilized oocyte.” For that reason, the new class name ZYGOTE was added to the terminology.

The revised definitions of OOCYTE and SPERM are backward compatible with the old definitions.

Table 1 Revised Class Definitions and New Class Name

Revised Class Definitions		
Class Name v7.31 and prior	Old Definition v7.31 and prior	Revised Definition v7.32
EMBRYO	Early stage of development from fertilized oocyte to blastocyst.	The biological organism resulting from the development of the zygote, until eight completed weeks after fertilization, equivalent to 10 weeks of gestational age.
OOCYTE	Oocyte that has not undergone fertilization.	The female gamete.
SPERM	Sperm.	The male gamete.

New Class Name v7.32	
Class Name	Definition
ZYGOTE	A single cell resulting from fertilization of a mature oocyte by a spermatozoon and before completion of the first mitotic division.

3 Attributes

3.1 Revised Attributes Definitions

Table 2 contains the old and revised definitions. The revised definitions of “Aspirated testicular,” “Cleavage stage,” “Morula,” and “Blastocyst” are backward compatible with the old definitions.

The new definition of “Washed” specifies washing by centrifugation; therefore, it is not fully backward compatible with the old definition. For that reason, the new attribute “Prepared” was created to refer to other methods of separation, see Section 3.3.

Table 2 Revised Attributes Definitions

Attribute Group	Attribute Name v7.31 and prior	Old Definition v7.31 and prior	Revised Definition v7.32
Sperm Procurement Method	Aspirated testicular	Sperm procured by aspiration from testis.	Sperm procured by percutaneous aspiration from testis.
Embryo Development Stage	Cleavage stage	Cleavage stage.	Embryo beginning at the two cell stage and up to, but not including, the morula stage.
	Morula	Morula.	Embryo after completion of compaction, typically 4 days after insemination or ICSI.
	Blastocyst	Blastocyst.	Embryo at the blastocyst stage, containing a fluid filled central cavity, an outer layer of cells and an inner group of cells. Typically occurs at day 5–6 after insemination.
Sperm Preparation	Washed	Viable sperm cells have been separated from other contents of the seminal fluid.	The ejaculate has been washed by centrifugation in a buffer solution.

3.2 Revised Attributes Names and Definitions

The names and definitions of attributes from the attribute group “Oocyte Maturation Stage” were revised.

Table 3 lists the old and revised attribute names and definitions. The attributes “GV” and “MII” were renamed as “Immature” and “Mature,” respectively. The revised definitions of these attributes are backward compatible with the old ones.

The attribute “MI” renamed as “Maturing” is not fully backward compatible because the new definition is broader and encompasses the MI attribute. For that reason, “Maturing” was incorporated to the terminology as a new attribute and the “MI” attribute was retired. See Sections 3.3 and 3.4.

Table 3 Revised Attributes Names and Definitions

Attribute Name v7.31 and prior	Old Definition v7.31 and prior	Revised Name v7.32	Revised Definition v7.32
GV	Germinal vesicle.	Immature	An oocyte at prophase of meiosis I (i.e., an oocyte at the germinal vesicle (GV) stage).
MI	Metaphase I.	Maturing	An oocyte that has progressed from prophase I but has not completed telophase I, thus does not exhibit the first polar body.
MII	Metaphase II.	Mature	An oocyte at metaphase of meiosis II, exhibiting the first polar body and with the ability to become fertilized.

3.3 New Attributes

Table 4 lists the new attributes created. As a result of the change in the definition of the existing attribute “Washed” (which now specifies washing by centrifugation), the new attribute “Prepared” was added to the attribute group “Sperm Preparation” to refer to other methods of separation.

The new attribute “Maturing” was added to the attribute group “Oocyte Maturation Stage” to replace the “MI” attribute since it has a broader definition that encompasses the MI attribute.

Table 4 New Attributes

Attribute Name	Definition
Prepared	Viable sperm cells have been isolated from other contents of the seminal fluid.
Maturing	An oocyte that has progressed from prophase I but has not completed telophase I, thus does not exhibit the first polar body.

3.4 Retired Attributes

Table 5 lists the retired attributes. The attribute “Fertilized oocyte” from the attribute group “Embryo Development Stage” was retired because it will be no longer necessary once the new class name ZYGOTE is implemented.

The attribute “MI” from the attribute group “Oocyte Maturation Stage” was retired because it is being replaced by the new attribute “Maturing” which has a broader definition that encompasses the “MI” attribute.

Table 5 Retired Attributes

Attribute Name	Definition
Fertilized oocyte	A fertilized oocyte that has not undergone cell division.
MI	Metaphase I.

4 Product Description Codes (PDCs)

4.1 Renamed PDCs

The attribute “MII” was renamed as “Mature.” The revised definition of this attribute is backward compatible with the old one. As a result, the PDCs R0047 and R0052 needed to be updated with the new attribute names. See Table 6.

Table 6 Renamed PDCs

PDC R0047	Product Description		
Before:	OOCYTE	MI	II
Updated to:	OOCYTE	Mature	

PDC R0052	Product Description		
Before:	OOCYTE	Not cryopreserved	MI
Updated to:	OOCYTE	Not cryopreserved	Mature

4.2 New PDCs

Table 7 lists the new PDCs created. The PDCs R0058, R0055, and R0056 were created because the new class name ZYGOTE was added to the terminology.

The PDC R0057 was created with the new attribute “Prepared.”

Table 7 New PDCs

PDC	Product Description
R0058	ZYGOTE
R0055	ZYGOTE Not cryopreserved
R0056	ZYGOTE Cryopreserved by vitrification
R0057	SPERM Ejaculated Prepared

4.3 Retired PDC

The PDC R0046 was retired since the attribute “Fertilized oocyte” was retired (it will be no longer necessary once the new class name ZYGOTE is implemented). See Table 8.

Table 8 Retired PDC

PDC	Product Description
R0046	EMBRYO Cryopreserved by vitrification Fertilized oocyte Day 1