



Terumo Medical Corporation
2101 Cottontail Lane
Somerset, NJ 08873

June 5, 2007

Dear Terumo Blood Bag Customer,

Terumo is pleased to announce the introduction of our Interim Codabar/*ISBT 128* blood bag label that incorporates Codabar and *ISBT 128* features. You can expect to see the label appearing on Terumo Blood Bag sets manufactured after April 2, 2007 and you should begin receiving them at your facility during the months of July and August¹. Please see the Table in Appendix A for a list of initial product codes and lot numbers with the interim label.

The intent of this label is to assist Blood Centers during the transition period and conversion from the current Codabar format to the *ISBT 128* Standard.

Terumo's Interim Codabar/*ISBT 128* blood bag labels are approved by FDA and incorporate elements that allow conformance to the following standards:

- (Draft) August 1989 "Guidelines for the Uniform Labeling of Blood and Blood Components" (Codabar standard)
- September 2006 "Guidance for Industry Recognition and Use of a Standard for Uniform Blood and Blood Component Container Labels" ("United States Industry Consensus Standard for the Uniform Labeling of Blood and Blood Components Using *ISBT 128*," version 2.0.0, dated November 2005)

To assist blood centers during the transition period, the interim label includes the following (See Appendix B):

- Increased label height to accommodate the required *ISBT128* manufacturer's product information and lot number.
- A shaded zone on the collection bag to guide placement of the *ISBT 128* donor identification number label.
- Machine readable manufacturer's product information and lot number with eye readable interpretation located below the bar codes. See Appendix C for cross reference table between Terumo catalog number and *ISBT 128* manufacturer's product code.
- Terumo eye readable catalog number (example BB*AGQ506A2) located above manufacturer's product information remains unchanged.
- Codabar information remains unchanged.

Should you have any questions, please feel free to contact your Territory Manager, or contact me directly at (800) 283-7866 ext. 4993 or by email at nathan.hecht@terumomedical.com.

Sincerely,

A handwritten signature in blue ink that reads "Nathan Hecht".

Nathan W. Hecht
Product Manager
Transfusion Products

¹ Arrival dates may vary depending on the product code ordered.

Appendix – A

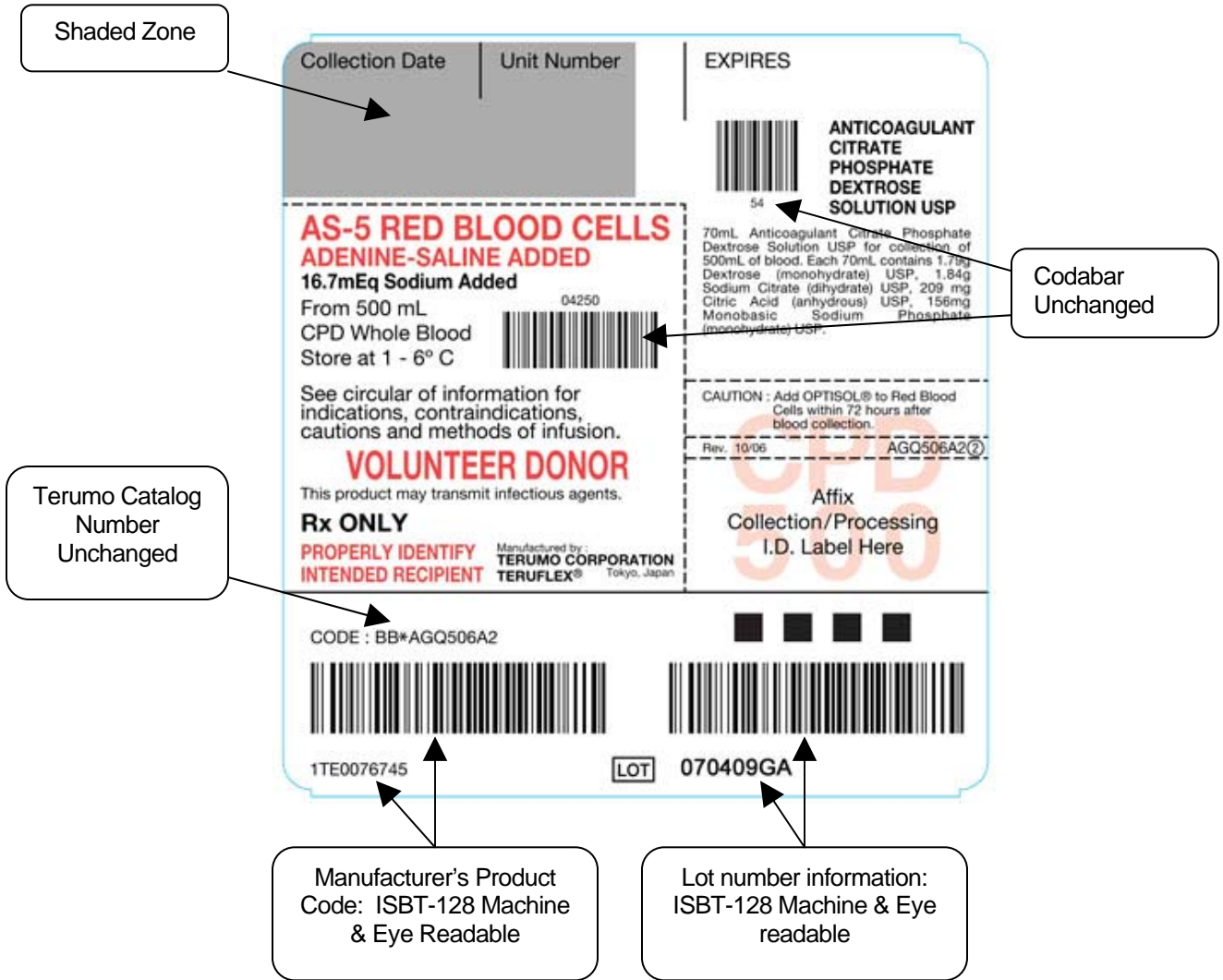
CPDA-1	
Terumo Catalog Number	Initial Lot Number
BB*SCD456A	070411GV
BB*SCD456A3	070528GW
BB*SCD456A4	070416GV
BB*SCD506A3	070416GW
BB*DCD456A	070601GV
BB*DCD456A3	070417GV
BB*DCD456A4	070416GX
BB*DCD506A3	070417GW
BB*TCD456A4	070417GY
BB*QCD456A3	070417GX
BB*QCD506A3	Not Identified Yet *

CPD / OPTISOL®	
Terumo Catalog Number	Initial Lot Number
BB*AGD456A	070416GB
BB*AGD456A2	070405KM
BB*AGD456A3	070420AF
BB*AGD506A2	070404KK
BB*AGD506A3	070405AG
BB*AGT456A	070416GC
BB*AGT456A2	070417GA
BB*AGT456A3	070413GA
BB*AGT506A2	070402GA
BB*AGT506A3	070411GA
BB*AGT506A2T	070412GA
BB*AGQ456A	Not Identified Yet *
BB*AGQ456A2	Not Identified Yet *
BB*AGQ506A2	070409GA

IMUFLEX®	
Terumo Catalog Number	Initial Lot Number
BB*WGQ506A2	070409KK
BB*LGQ506A6	Not Identified Yet *

* Initial lot numbers have not yet been assigned for these product codes.

Appendix – B



Appendix – C

CPDA-1	
Terumo Catalog Number	Manufacturer's ISBT 128 Product Code (Primary Bag)
BB*SCD456A	1TE0070327
BB*SCD456A3	1TE0076195
BB*SCD456A4	1TE0070329
BB*SCD506A3	1TE0076199
BB*DCD456A	1TE0070225
BB*DCD456A3	1TE0076197
BB*DCD456A4	1TE0070227
BB*DCD506A3	1TE0076201
BB*TCD456A4	1TE0070389
BB*QCD456A3	1TE0076187
BB*QCD506A3	1TE0076191

CPD / OPTISOL®	
Terumo Catalog Number	Manufacturer's ISBT 128 Product Code (Primary Bag)
BB*AGD456A	1TE0070105
BB*AGD456A2	1TE0076693
BB*AGD456A3	1TE0076099
BB*AGD506A2	1TE0076689
BB*AGD506A3	1TE0074995
BB*AGT456A	1TE0070167
BB*AGT456A2	1TE0076695
BB*AGT456A3	1TE0076097
BB*AGT506A2	1TE0076691
BB*AGT506A3	1TE0075961
BB*AGT506A2T	1TE0076747
BB*AGQ456A	1TE0070123
BB*AGQ456A2	1TE0076949
BB*AGQ506A2	1TE0076745

IMUFLEX®	
Terumo Catalog Number	Manufacturer's ISBT 128 Product Code (Primary Bag)
BB*WGQ506A2	1TE0077585
BB*LGQ506A6	1TE0077481