

STERILE CORD BLOOD COLLECTION UNIT (MSC123D)- anticoagulant citrate phosphate dextrose injection, solution
Maco Productions

STERILE CORD BLOOD COLLECTION UNIT (MSC123D)

MACO BIOTECH Collection- Sterile Cord Blood Collection Unit (MSC123D)

The MSC123D Sterile Cord Blood Collection Unit consists of 250 mL collection bag containing 35 mL of Anticoagulant Citrate Phosphate Dextrose Solution USP (CPD) and one 12 gauge needle with a protective shield (SECUVAM) for the used needle. Sterile, non-pyrogenic fluid path. Sterilized by steam.

Rx only.

This product is not made with natural rubber latex.

INDICATIONS AND USAGE

MSC123D - For collection of up to 210 mL of umbilical cord blood. Use aseptic technique.

WARNINGS

- Avoid contact with sharp objects.
- Do not irradiate collected cord blood or components.
- Making multiple punctures of the umbilical cord to increase collection volume may increase the risk of contamination.

PRECAUTIONS

- The kit within its aluminum outer overwrap must be stored at room temperature and protected from freezing: do not refrigerate or freeze.
- DO NOT use if the overwraps or bags show any signs of alteration.
- This is a single use sterile kit: under no circumstances should it be reused.
- For optimal cord blood quality it is recommended to maintain the cord blood at an ambient temperature (18-26°C / 64.4-78.8°F) or cold temperature (4-2°C / 39.2-53.6°F) and process within 48 hours of collection.^{1,2,3}.

If the collection volume is less than 60 mL, the cord blood should be processed within 24 hours of collection.

HOW SUPPLIED

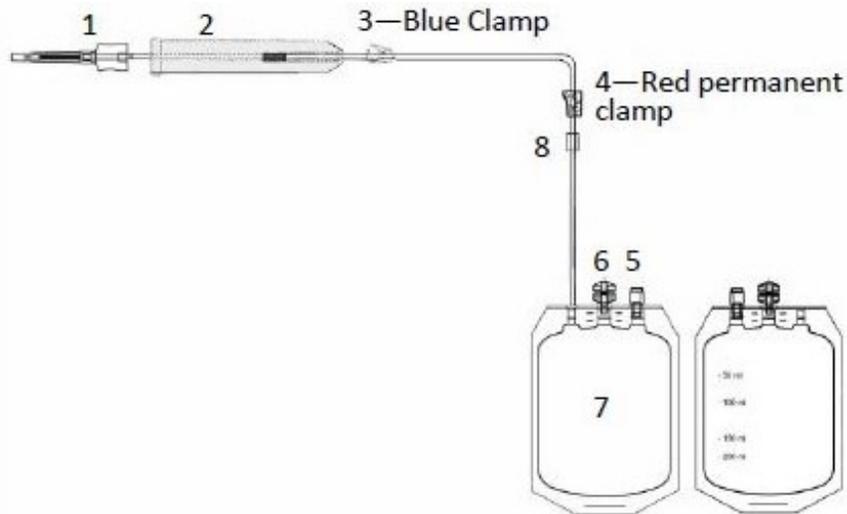
MSC123D Sterile Cord Blood Collection Unit contains:

- 250 mL collection bag containing 35 mL CPD
- 1- 12 gauge needle with a protective shield (SECUVAM) for used needle
- Printed volume indications as visual aid to approximate the volume.

INSTRUCTIONS FOR USE

Carefully Read All the Instructions Before Use

Representative Product Drawing



- | | |
|-----------------------|------------------|
| 1 needle | 5 injection site |
| 2 needle protector | 6 outlet port |
| 3 blue clamp | 7 bag |
| 4 red permanent clamp | 8 safety ring |

REF MSC123D

I. PREPARATION

1. Before use, verify the integrity of the collection unit (overwrap, outlet ports, tubing...).
2. Only contents inside the inner wrap are sterile and acceptable for use in a sterile field if pouch is unopened and undamaged.

II. COLLECTION PROCEDURE

1. Close the clamp 3 (clamp 4 should remain open).
2. After clamping and sectioning of the umbilical cord, place the collection bag on a mixer and perform a venipuncture at lower end of the umbilical cord with needle 1.
Note: Umbilical venipunctures can be done before or after the expulsion of the placenta according to your local procedures.
3. Open clamp 3.
4. Stimulate cord blood flow by massaging the cord from the top downward to increase

volume of collection.

5. When collection is completed, close clamp 3.

6. Remove needle 1 and slide down SECUVAM 2 (needle protector) over needle 1.

III. ADDITION OF CORD BLOOD FROM THE TUBE TO THE SAMPLING POUCH

1. Move clamp 3 at the top of the collection line close to the needle protector 2

2. Using a blood stripper, strip the tubing from the top of the tube towards the safety ring expelling the blood in the tubing into collection bag 7.

3. Repeat this operation 3 times.

4. Mix collection bag 7.

5. Close clamp 3.

IV. END OF COLLECTION

1. Close clamp 4 to secure the collection above the safety ring 8.

2. Seal the tubing above the clamp 4.

3. Fill in collection volume on the collection bag label.

4. For optimal cord blood quality, maintain the cord blood at an ambient temperature (18-26°C / 64.4-78.8°F) or cold temperature (4-12°C / 39.2-53.6°F) and process within 48 hours of collection.^{1,2,3}

If the collection volume is less than 60 mL, the cord blood should be processed within 24 hours of collection.

VI. CONTACT INFORMATION

Manufactured for United States of America (U.S.A.) by Maco Productions Polonia, Sp. z o.o. ul. Szwajcarska 22, 54-405 Wroclaw, POLAND +48 71 37 60 110

For consumer information contact:

Distributed by Uneklo USA, Inc., dba Macopharma USA, 3075 Breckinridge Boulevard, Suite 405, Duluth, GA 30096, USA (770) 270-6867

VII. REFERENCES

1. Pope, B., Mitsakos, K., Bilgin, A., Hokin, B. and Grant, R: Predicting overall viability of cord blood harvests. Transfusion 2012; 52:1079-1085

2. Salge-Bartels U. Huber. M, Kleiner K, Volkens P, Seitz R, Heiden M: Evaluation of Quality Parameters for Cord Blood Donations, Transfus Med Hemother 2009; 36:317-324

3. Prof. Dr.Kogler, Jose Carreras CBB, medical Center, University of Duesseldorf : General information on the institution and the production facility of the Jose Carreras Cord Blood Bank. 2014

PRINCIPAL DISPLAY PANEL

LABELS

Collection Bag Label

CORD BLOOD COLLECTION BAG

Date/Time of Collection

Affix Donor Collection La

Expiry

Collection Facility Information

HPC, Cord Blood

Approx. In 35 mL CPD



YYYY-MM



STERILE



Use only. Sterile and non pyrogenic fluid pathway.
Do not irradiate.
Manufactured for Unelko USA, Inc.,
d/b/a MacsPharma USA by:
Maco Productions Polska Sp. z o.o.
ul. Sewajcarska 22
54-405 Wrocław, POLAND

ANTICOAGULANT
CITRATE PHOSPHATE DEXTROSE
35 mL Anticoagulant Citrate P
Solution USP for collection of
Each 35 mL of anticoagulant c
Sodium Citrate (dihydrate) US
Dextrose (monohydrate) USP
Citric acid (monohydrate) USP
Mono basic Sodium Phosphat
pH may have been adjusted w/

Use only if clear.
ONLY THE CONTENTS INSIDE
TRANSPARENT OVERWRAP
BE PLACED ON THE STERILE

REF

MSC123D

LOT

123456



1MAMSC123D

1

123456

Overwrap Label



STERILE CORD BLOOD COLLECTION UNIT

ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE (CPD) SOLUTION USP
for collection of up to 210 mL of blood

Each unit consists of a collection bag with 35mL of CPD solution.

Each 35mL of CPD solution contains:

0.92 g Sodium Citrate (dihydrate) USP ; 0.89 g Dextrose (monohydrate) acid (monohydrate), USP ; 87.9 mg Mono basic Sodium Phosphate (dihy

For only. Sterile, nonpyrogenic fluid path. Sterilized by steam. See accord for use. Store below 25°C (77°F). Do not refrigerate or freeze.

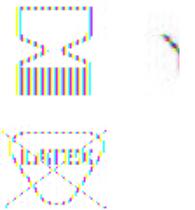
ONLY contents inside the INNER WRAP are sterile and acceptable for use if pouch is unopened and undamaged. Inspect integrity.

1 Unit

PRODUCT: REF A

LOT 1

Manufactured for Unidelo USA, Inc.,
dba Macopharma USA by:
Maco Productions Polonia Sp. z o.o.
ul. Szewajcarska 22
54-405 Wrocław, POLAND



STERILE CORD BLOOD COLLECTION UNIT (MSC123D)

anticoagulant citrate phosphate dextrose injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:14498-005
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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SODIUM CITRATE (UNII: 1Q73Q2JULR) (ANHYDROUS CITRIC ACID - UNII:XF417D3PSL)	SODIUM CITRATE	0.92 g in 35 mL
DEXTROSE MONOHYDRATE (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SL0G7R0OK)	DEXTROSE MONOHYDRATE	0.89 g in 35 mL
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) (ANHYDROUS CITRIC ACID - UNII:XF417D3PSL)	ANHYDROUS CITRIC ACID	114.5 g in 35 mL
SODIUM PHOSPHATE, MONOBASIC, DIHYDRATE (UNII: 5QWK665956) (PHOSPHATE ION - UNII:NK08V8K8HR)	SODIUM PHOSPHATE, MONOBASIC, DIHYDRATE	87.9 g in 35 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14498-005-01	1 in 1 KIT		
1		35 mL in 1 KIT; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	BN125552	10/02/2020	

Labeler - Maco Productions (265492868)

Revised: 12/2025

Maco Productions