

STERILE CORD BLOOD COLLECTION UNIT (MSC128D)- anticoagulant citrate phosphate dextrose solution injection, solution
Maco Productions

Sterile Cord Blood Collection Unit (MSC128D)

MACO BIOTECH Collection - Sterile Cord Blood Collection Unit (MSC128D)

The MSC128D Sterile Cord Blood Collection Unit consists of 300 mL collection bag containing 21 mL of Anticoagulant Citrate Phosphate Dextrose Solution USP (CPD), a 40 mL rinsing bag containing 8 mL of CPD and two 12 gauge needles 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

MSC128D - For collection of up to 200 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

- 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 (4-12°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.

HOW SUPPLIED

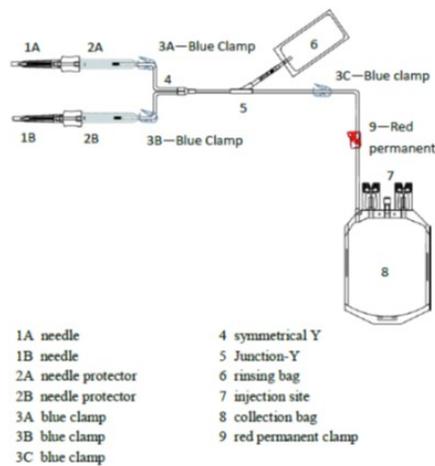
MSC128D Sterile Cord Blood Collection Unit contains:

- 300 mL collection bag containing 21 mL CPD
- 40 mL rinsing bag containing 8 mL CPD
- 2-12 gauge needles with a protective shield (SECUVAM) for used needle
- Graduation label as visual aid to approximate the volume.

INSTRUCTIONS FOR USE

Carefully Read All the Instructions Before Use

Representative Product Drawing



REF MSC128D

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 all clamps 3A, 3B and 3C (clamp 9 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 first needle 1A.

Note: Umbilical venipunctures can be done before or after the expulsion of the placenta according to your local procedures.

3. Open clamps 3A and 3C.
4. Stimulate cord blood flow by massaging the cord from the top downward to increase volume of collection.
5. When collection is completed, close clamps 3A and 3C.
6. Remove needle 1A and slide down SECUVAM 2A (needle protector) over needle 1A.
7. If necessary, perform a second umbilical venipuncture on the upper part of the umbilical cord (near the mother)

[See Warnings]:

- a. Open clamps 3B and 3C.
- b. Perform venipuncture on the umbilical cord using other needle 1B.
- c. When collection is completed, close clamps 3B and 3C.
- d. Remove needle 1B and slide down SECUVAM 2B (needle protector) over needle 1B.

III. RINSING OF COLLECTION LINE

1. Open clamp 3C.
2. Snap the break-away cannula on top of rinsing bag 6.
3. Roll up bag 6 on itself to empty 8 mL of anticoagulant (CPD) in the tubing to push the cord blood remaining in the tubing into the collection bag. Do not strip the tubing.
4. Close clamp 3C.
5. Proceed to section V END OF COLLECTION if collection volume is less than 150 mL. For collection volumes greater than 150 mL, proceed to section IV ADDITION OF ANTICOAGULANT INTO THE COLLECTION BAG.

IV. ADDITION OF ANTICOAGULANT INTO THE COLLECTION BAG

Use this step only for collection volumes greater than 150 mL.

1. Seal the tubing above Y junction 5.
2. Move clamp 3C near to Y junction 5.
3. Using a blood stripper, strip the tubing from Y junction 5 towards collection bag 8 expelling the anticoagulant in the tubing into collection bag 8.
4. Repeat this operation 3 times.
5. Mix collection bag 8.
6. Close clamp 3C.
7. Proceed to section V END OF COLLECTION.

V. END OF COLLECTION

1. □Close clamp 9 to secure the collection.
2. Seal the tubing between clamp 9 and collection bag 8.
3. Fill in collection volume and CPD volume on the collection bag label. The amount of CPD is as follows:
 - a. 21 mL - if no additional CPD is added.
 - b. 29 mL - if additional 8 mL CPD from rinsing bag is added to the collection bag as directed in section IV.
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).□

VI. CONTACT INFORMATION

Manufactured for United States of America (U.S.A.) and Canada by Maco Productions Polonia, Sp. z o.o.

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For consumer information contact:

- For the U.S.A.: Distributed by Uneklo USA, Inc. dba Macopharma USA

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(770) 270-6867

- For Canada: Distributed by Macopharma Canada

1200 McGill College, Suite 1715, Montreal (Quebec) H3B 4G7
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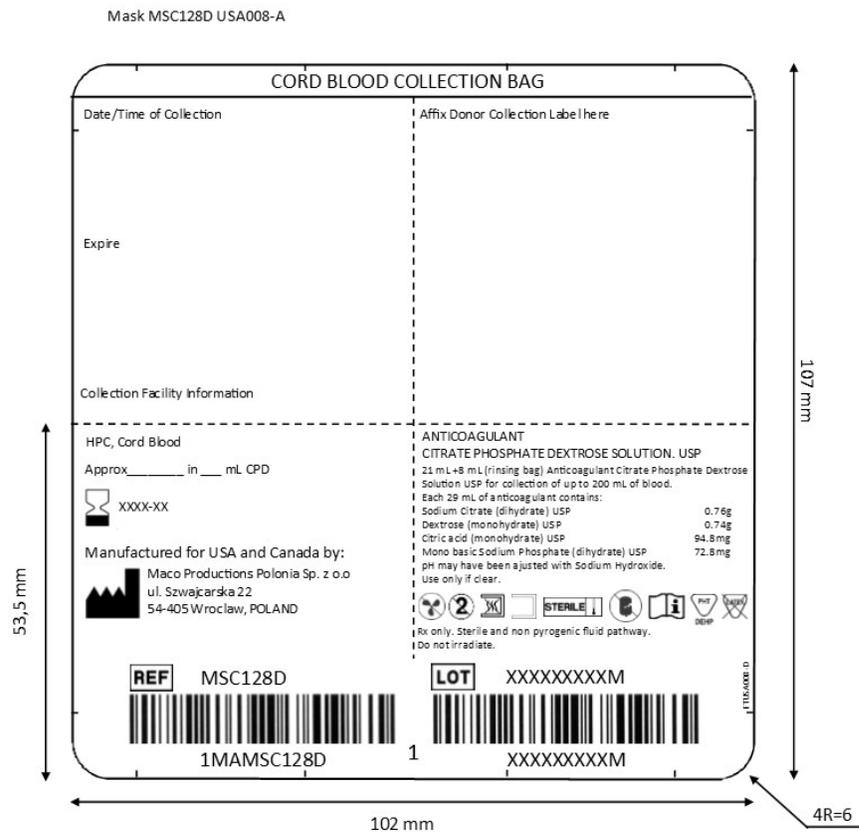
VII. REFERENCES

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, Volkers 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

LABELS

Collection Bag Label



Overwrap Label

Mask MSC128D USA009-A

macopharma
DESIGNED FOR LIFE

STERILE CORD BLOOD COLLECTION UNIT

ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE (CPD) SOLUTION USP
for collection of up to 200 mL of blood

Each unit consists of a collection bag with 21mL + 8mL (rinsing bag) of CPD solution.
Each 29mL of CPD solution contains:
0.76 g Sodium Citrate (dihydrate) USP ; 0.74 g Dextrose (monohydrate) USP ; 94.8 mg Citric acid (monohydrate), USP ; 72.8 mg Mono basic Sodium Phosphate (dihydrate), USP.

Rx only. Sterile, nonpyrogenic fluid path. Sterilized by steam. See accompanying instructions 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 in a sterile field, if pouch is unopened and undamaged. Inspect integrity.

1 Unit

PRODUCT: **REF** MSC128D

LOT XXXXXXXXXM

XXXX-XX

Manufactured for USA and Canada by:
Maco Productions Polonia Sp. z o.o
ul. Szwajcarska 22
54-405 Wrocław, POLAND

107 mm

102 mm

4R=6

REF MSC128D

STERILE CORD BLOOD COLLECTION UNIT (MSC128D)

anticoagulant citrate phosphate dextrose solution injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:14498-004
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM CITRATE (UNII: 1Q73Q2JULR) (ANHYDROUS CITRIC ACID - UNII:XF417D3PSL)	SODIUM CITRATE	0.76 g in 29 mL
DEXTROSE MONOHYDRATE (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SL0G7R0OK)	DEXTROSE MONOHYDRATE	0.74 g in 29 mL
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) (ANHYDROUS CITRIC ACID - UNII:XF417D3PSL)	ANHYDROUS CITRIC ACID	94.8 mg in 29 mL
SODIUM PHOSPHATE, MONOBASIC, DIHYDRATE (UNII: 5QWK665956) (PHOSPHATE ION - UNII:NK08V8K8HR)	SODIUM PHOSPHATE, MONOBASIC, DIHYDRATE	72.8 mg in 29 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14498-004-01	1 in 1 KIT		
1		29 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	12/21/2016	

Labeler - Maco Productions (265492868)

Registrant - Maco Productions (265492868)

Establishment

Name	Address	ID/FEI	Business Operations
Maco Productions Polonia sp zoo		367387284	manufacture(14498-004)

Revised: 12/2017

Maco Productions