

MACO BIOTECH *Collection* - STERILE CORD BLOOD COLLECTION UNIT

STERILE CORD BLOOD COLLECTION UNIT

The MSC1207DD Sterile Cord Blood Collection Unit consists of 300 mL collection bag containing 27 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

MSC1207DD - For collection of up to 250 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

MSC1207DD Sterile Cord Blood Collection Unit contains:

- 300 mL collection bag containing 27 mL CPD
- 40 mL rinsing bag containing 8 mL CPD
- 2– 12 gauge needles with a protective shield (SECUVAM) for used needle

INSTRUCTIONS FOR USE

Carefully Read All the Instructions Before Use

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 200 mL. For collection volumes greater than 200 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 200 mL.

1. Seal the tubing above the 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. 27 mL – if no additional CPD is added.
 - b. 35 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.

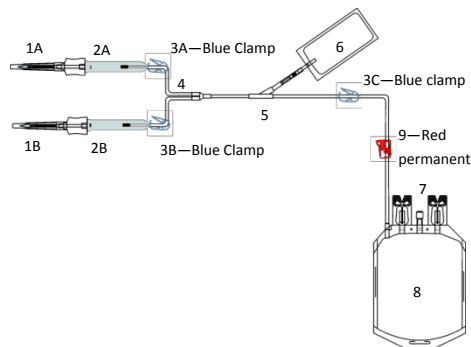
ul. Szwajcarska 22, 54-405 Wrocław, POLAND
+48 71 37 60 110

For consumer information contact:

- For the U.S.A.: Distributed by Unekko USA, Inc., dba Macopharma USA, 3675 Crestwood Parkway, Suite 260, Duluth, GA 30096, USA
(770) 270-6867
- For Canada: Distributed by Macopharma Canada, 1200 McGill College, suite 1715, Montreal (Quebec) H3B 4G7
(514) 866-2222

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 CBBB, medical Center, University of Duesseldorf : General information on the institution and the production facility of the Jose Carreras Cord Blood Bank. 2014



- | | |
|---------------------|-----------------------|
| 1A needle | 4 symmetrical Y |
| 1B needle | 5 Junction-Y |
| 2A needle protector | 6 rinsing bag |
| 2B needle protector | 7 injection site |
| 3A blue clamp | 8 collection bag |
| 3B blue clamp | 9 red permanent clamp |
| 3C blue clamp | |

REF MSC1207DD

Read the instructions for use

STERILE Sterilized using steam or dry heat

2 Do not re-use

Store below 25°C. Do not refrigerate or freeze

Avoid excess humidity

Keep away from sunlight

REF Code number

LOT Lot number

Expiry date

Non-pyrogenic fluid path

Do not use if the bag presents any visible sign of deterioration

Presence of Phthalates

Not made with natural rubber latex

Fluid path

NOTUSA12/D 2016-12-14

For Canada: DIN number: 02444100



macopharma
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ul. Szwajcarska 22
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STERILE CORD BLOOD COLLECTION UNIT

ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE (CPD) SOLUTION USP
for collection of up to 250 mL of blood

Each unit consists of a collection bag with 27mL + 8mL (rinsing bag) of CPD solution.
Each 35mL of CPD solution contains:
0.92 g Sodium Citrate (dihydrate) USP ; 0.89 g Dextrose (monohydrate) USP ; 114.5 mg Citric acid (monohydrate), USP ; 87.9 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

LOT XXXX XXXXX

PRODUCT: REF MSC1207DD

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

XX— XXXX

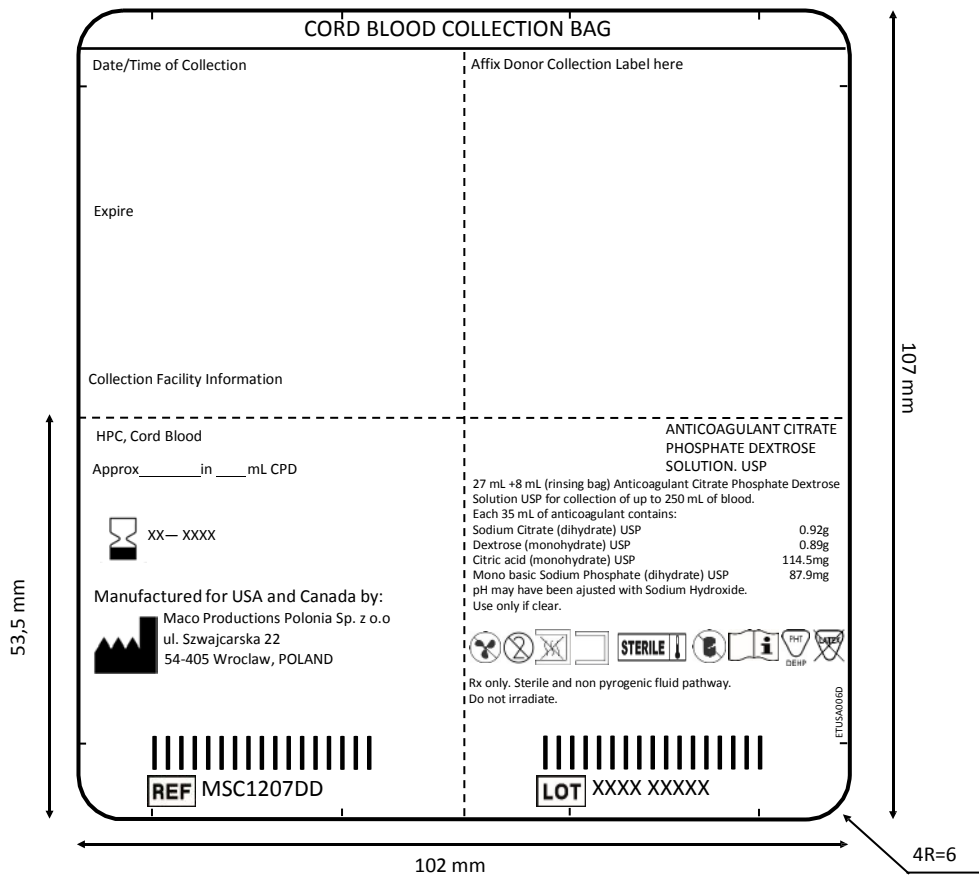


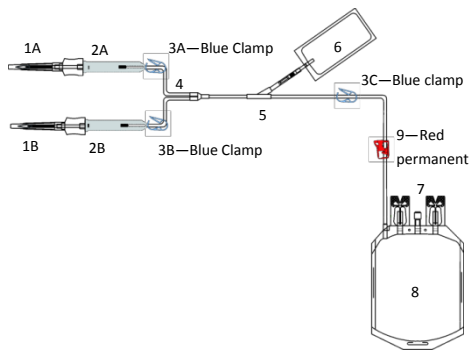
ETUSK007E

107 mm

102 mm

4R=6





- 1A needle
- 1B needle
- 2A needle protector
- 2B needle protector
- 3A blue clamp
- 3B blue clamp
- 3C blue clamp
- 4 symmetrical Y
- 5 Junction-Y
- 6 rinsing bag
- 7 injection site
- 8 collection bag
- 9 red permanent clamp

REF MSC1208DD

The MSC1208DD 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

MSC1208DD - 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

MSC1208DD 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

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 the 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

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ul. Szwajcarska 22, 54-405 Wrocław, POLAND

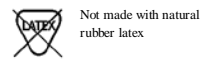
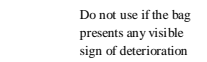
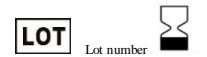
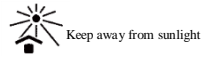
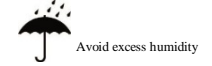
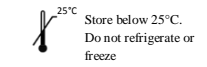
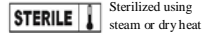
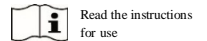
+48 71 37 60 110

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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, 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



NOTUSA08/D 2016-12-14

For Canada: DIN number: 02444100

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ul. Szwajcarska 22
54-405 Wrocław, POLAND

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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

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

LOT XXXX XXXXX

PRODUCT: REF MSC1208DD

 XX— XXXX

















ETUSKADIBE

107 mm

102 mm

4R=6

CORD BLOOD COLLECTION BAG

Date/Time of Collection	Affix Donor Collection Label here
Expire	
Collection Facility Information	
HPC, Cord Blood Approx _____ in _____ mL CPD  XX—XXXX Manufactured for USA and Canada by:  Maco Productions Polonia Sp. z o.o. ul. Szwajcarska 22 54-405 Wroclaw, POLAND	ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION. USP 21 mL +8 mL (rinsing bag) Anticoagulant Citrate Phosphate Dextrose Solution USP for collection of up to 200 mL of blood. Each 29 mL of anticoagulant contains: Sodium Citrate (dihydrate) USP 0.76g Dextrose (monohydrate) USP 0.74g Citric acid (monohydrate) USP 94.8mg Mono basic Sodium Phosphate (dihydrate) USP 72.8mg pH may have been adjusted with Sodium Hydroxide. Use only if clear.           Rx only. Sterile and non pyrogenic fluid pathway. Do not irradiate.
 REF MSC1208DD	 LOT XXXX XXXXX

53,5 mm

107 mm

102 mm

4R=6