STERILE CORD BLOOD COLLECTION UNIT

MSC1207DD Sterile Cord Blood Collection Unit contains:
- 4 symmetrical Y
- Junction-Y
- 6 rinsing bag
- 8 collection bag
- red permanent clamp
- blue clamp
- needle protector
- needle
- rinsing bag
- collection bag
- needle protector
- needle
- junction-Y
- blue clamp
- needle protector
- needle
- collection bag
- red permanent clamp
- blue clamp
- needle protector
- needle
- junction-Y

HOW SUPPLIED
- 300 mL collection bag containing 27 mL CPD
- 40 mL rinsing bag containing 8 mL CPD
- 2-12 gauge needles with a protective shield (SECUVMAM) 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, proceed to step II.

II. COLLECTION PROCEDURE
1. Close all clamps 3A, 3B and 3C (clamp 9 should remain open).
2. After clamping and actuating 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 veins must 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 complete, 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).

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 collection bag 8.
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 to near 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) and process within 48 hours of collection.

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 Wroclaw, POLAND
+48 71 37 61 110
For consumer information contact:
- For the U.S.A.: Distributed by Uniklo 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
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
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: MSC1207DD

Manufactured for USA and Canada by:
Maco Productions Polonia Sp. z o.o
ul. Szwajcarka 22
54-405 Wroclaw, POLAND
CORD BLOOD COLLECTION BAG

Date/Time of Collection

Affix Donor Collection Label here

HPC, Cord Blood

Approximate 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

27 mL + 8 mL [rinsing bag] Anticoagulant Citrate Phosphate Dextrose Solution USP for collection of up to 250 mL of blood.

Each 35 mL of anticoagulant contains:

- Sodium Citrate (dihydrate) USP: 0.92g
- Dextrose (monohydrate) USP: 0.89g
- Citric acid (monohydrate) USP: 114.5mg
- Mono-basic Sodium Phosphate (dihydrate) USP: 87.9mg

pH may have been adjusted with Sodium Hydroxide.

Rx only. Sterile and non-pyrogenic fluid pathway.

Do not irradiate.

RX MSC1207DD

LOT XXXX XXXXX
The MSC1208DD Sterile Cord Blood Collection Unit contains a collection bag containing 30 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 (SUVEAM) for the used needle.

Sterile, non-pyrogenic fluid path. Sterilized by steam.

• 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.
• Avoid excessive humidity.
• Do not freeze or use outside recommended temperature range.
• Do not reuse.

**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). 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 of Anticoagulant Citrate Phosphate Dextrose Solution USP (CPD), a 40 mL rinsing bag containing 8 mL of CPD
- 2–12 gauge needles with a protective shield (SUVEAM) for used needle
- Graduation label as visual aid to approximate the volume
- Shield (SUVEAM) for the 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, outbreak 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.
3. Uniblank venules can be punctured before or after the expulsion of the placenta according to your local procedures.
4. Open clamps 3A and 3C.
5. Stimulate cord blood flow by massaging the cord from the top downward to increase volume of collection.

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 IV END OF COLLECTION if collection volume is less than 150 mL. For collection volumes greater than or equal to 150 mL, proceed to section IV ADDITION OF ANTIMICROBIAL INTO THE COLLECTION BAG.

IV. ADDITION OF ANTIMICROBIAL 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 the 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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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 Wroclaw, POLAND

PRODUCT: XXXX XXXXX
LOT XXXX XXXXX
REF MSC1208DD
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.