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# User Guide

## A Disposable
## Cord Blood Collection Device

# TABLE OF CONTENT





## *Introduction*

The **SituGen** Device and **SituKit**, supplied in two separate kits, have been carefully designed and packaged. They contain all the necessary accessories required for efficient collection of umbilical cord blood (UCB) following delivery.

Read these instructions carefully before starting to learn how to collect the blood most effectively. This document includes detailed, precise instructions for collecting UCB, and it is important to keep it near you during the collection procedure.

## Please Note:

- UCB **must be collected by a trained staff member** who **does not** in any way take part or assist in the delivery process.
- UCB collection **must start immediately after the delivery of the infant (prior to placenta delivery)**, to guarantee maximum blood collection.
- The kit and all of its components are sterile and are double-packed to use in operating rooms for Caesarian section.
- Please keep all equipment and surfaces completely sterile throughout the collection procedure.
- The SituGen Device and the SituKit items are delicate and must be handled with care to avoid breaking or damaging them.
- This document also contains troubleshooting instructions for handling problems that may occur during preparation and collection. It is important to read all the instructions before starting the collection and to follow them during the procedure.

## *Contents of the Kits*

There are two (2) separate kits: 1 - The **SituGen** Device and 2 - The **Situkit** which contains three numbered compartments (marked as #1 - #2 - #3), containing separately packed and sterile accessories:

| **SituGen Kit** | |
|---|---|
| *Item* | *Qty.* |
| Two parts – upper & lower (clear chamber with filter and connector) | *1* |



## The Situkit

### Compartment #1

**Accessories**

| # | *Item* | *Qt.* |
|---|---|---|
| 1 | White/Blue paper towel | *1* |
| 2 | Green paper towel | *1* |
| 3 | Umbilical clamp scissors (reopen able) | *2* |
| 4 | Scissors for cutting the umbilical cord | *1* |
| 5 | Ruler for measuring the length of the umbilical cord residual | *1* |

### Compartment #2

**Disinfection items**

| # | *Item* | *Qt.* |
|---|---|---|
| 1 | Large preps for disinfecting the umbilical cord | *2* |
| 2 | Syringe with disinfecting solution | *1* |
| 3 | Small preps for disinfecting the placenta | *1* |

### Compartment #3

**Collection & Dispatch items**

| # | *Item* | *Qt.* |
|---|---|---|
| 1 | Blood collection bag (350 ml), with anticoagulant, connected to a valve | *1* |
| 2 | Syringe with anticoagulant connected to a needle, for direct blood collection from the placenta, after collection with SituGen | *1* |
| 3 | Sealed tape plastic bag for dispatching the collection bag | *1* |
| 4 | Sealed tape plastic bag for dispatching the placenta blood syringe to the laboratory | *1* |

**<u>Important:</u> Keeping all accessories, surfaces and tools sterile is vital for successful collection of UCB.**

**Collection is performed in 3 main stages:**
**1 Preparation 2 Disinfection 3 Collection**

# *1. Preparation*

## 1.1 Preparation for delivery

### A. Preparing the main work surface


1. Prepare the main working surface beneath the mother, spread out the White/Blue towel.
2. Disinfect the working surface with alcohol.
3. Place the **SituGen** and the **SituKit** kits on the working surface.
4. Open the outer packaging of the two kits and make sure that the items look intact and that their contents are complete.
5. From Compartment #1 of the **SituKit**, take the white absorbent paper towel and place it on the working surface.
6. Place this user guide within sight.

**<u>Important</u>: During collection, the placenta must be above the SituGen Device and the umbilical cord, and the umbilical cord must be above the SituGen Device.**



### B. Preparing the surface for placement of the placenta

7. Prepare a secondary surface and/or receptacle for receiving the placenta above the main work surface, in case the placenta is expelled during collection.
8. Disinfect the placenta work surface and/or receptacle with alcohol.
9. Take the green paper towel from compartment #1 and place it on the placenta work surface.

## 1.2 Preparation for collection

### A. Following the beginning of delivery


1. Take the two device parts (the upper part and the lower, clear chamber) from the **SituGen** kit and open the packaging.
2. Open the hanging hook of the device.
3. Place the two parts of the SituGen Device – the upper part and the lower (clear chamber) – on the work surface, with the ***UP*** symbol pointing upwards.

### B. Preparation of the Umbilical Cord


4. After delivery, immediately following the clamping of the infant's cord (with the hospital clamp), use the clamping scissors from compartment #1 to clamp the cord about 2 cm from the infant's clamp.
5. Cut the umbilical cord between the two clamps using the cutting scissors from compartment #1.


6. Hold the bottom end of the umbilical cord. Using the ruler, measure 5 inches (12.5 cm) from the bottom clamp and drain the blood in the measured section of the umbilical cord by milking it upwards, from the clamp towards the placenta. Hold the cord tightly to prevent the blood from draining downwards.

7. While tightly holding the cord, measure 5 inches (12.5 cm) from the clamping scissors upwards.
8. Clamp above the drained area (while the cord should be attached to clamp V bottom) using the additional clamping scissors from compartment #1, allowing the cord to hang freely. In total you will now have about 5 inches (12.5cm) of cord to place into the SituGen Device.
9. Remove the lower clamping scissors from the cord and discard them.
10. Thoroughly clean the section of umbilical cord beneath the upper clamping scissors using the two large prep pads from compartment #2. This step is crucial for complete removal of maternal stem cells.




**Important: The presence of maternal cells in the sample may disqualify it for**

## C. Insertion of the Umbilical Cord to the SituGen Device

11. Pick up the upper part of the SituGen Device and place the cord onto the absorbent paper, keeping the clamping scissors adjacent to it.
12. Fix the clamping scissors onto the pin at the top of the upper part.
13. Make sure that at least 2 inches (5 cm) of cord are hanging off the end, and close the device carefully.
14. Pick up the lower part of the SituGen Device (the clear chamber) and insert the end of the cord into the device, connecting the two units.
15. Make sure the end of the cord appears in the clear chamber. If necessary you can use your finger to push it through.






16. Insert the teeth of the upper part into the clear chamber (make sure all teeth are inside) and lock the two parts by turning the upper part in the direction of the “Lock" arrow until it locks into the teeth of the clear chamber.


## 2. Disinfecting the Clear (bottom) chamber

1. Slightly loosen the clamping scissors until a drop of blood drips into the clear chamber and quickly retighten the clamping scissors.
2. Pick up the syringe with the Chlorhexidine solution from compartment #2, and connect it to the bottom of the device by screwing it tightly into the connector.
3. Slowly inject the solution until the clear chamber is totally full and a few drops of solution emerge from the filter on the right hand side.
4. Wait for about 10 seconds with the syringe connected to the device.
5. Drain all of the disinfectant solution back into the same syringe. Then disconnect and discard it.

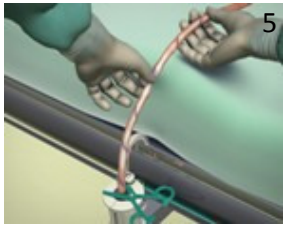


## 3. Collection

### 3.1 Collecting the blood from the Umbilical Cord

1. Remove the valve cup of the blood collection bag (350 ml) placed in compartment #3 and connect the valve to the connector at the bottom of the device.
2. Hang the device under the mother. The blood bag should be positioned beneath the device. Make sure the cord is loose.


3. Open the clamping scissors and allow free blood flow.
4. Let the blood flow through the clear chamber into the collection bag.
5. Every few seconds, drain the full length of the cord by milking it from the placenta towards the device. Make sure you hold the cord firmly in place in one hand, while milking it with the other, to prevent the placenta from being expelled.
6. Continue to collect as much blood as possible. Every drop is important.
7. Disconnect the collection bag from the device and shake it well.


## 3.2 Placental collection

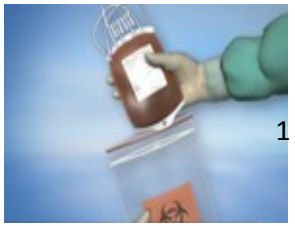
1. Once collection from the umbilical cord is complete, wait for the placenta to be expelled. Check if there's any blood remaining, and if so, collect the blood remaining in the placenta.
2. Identify the blood-rich veins in the placenta (on the side that was connected to the umbilical cord); full veins protrude more.
3. Disinfect the vein using one of the small prep pads from compartment #2.
4. Using the empty syringe connected to the needle (both located in compartment #3), collect all of the blood from each of the full veins until the placenta is completely drained.
5. Please remember that every drop is important.
6. Disconnect the needle and discard it.

**<u>Important:</u> If the placenta is ejected during the collection, simply place it on the placenta surface and continue the collection procedure.**



## *Dispatch to the laboratory*

1. Carefully shake the collection bag and pack it in the provided sealing tape larger bag from compartment #3.
2. If the placenta syringe has been used, pack it in the syringe dispatch bag also provided in compartment #3.
3. Dispatch the blood bag together with the syringe (if used) as procedure requires, as quickly as possible.



# *Troubleshooting*

*This chapter provides solutions to possible problems that may occur during the preparation stage or during the collection procedure. There is a distinction made between essential items and accompanying accessories.* ***Cord blood banks are referred to as CBB.***

## *The Preparation Stage*

*Problem:* **The main package is open** (the internal packages remain sealed).
*Solution:* The kit is suitable only in a regular delivery. Do not use the kit for a Caesarian section, which requires double sterile packaging.

Problem: **The disinfection solution leaks from the syringe.**
Solution: The kit is not suitable for use - this must be reported to the CBB.

Problem: **Items are missing from the kit.**
*Solution:* **Lack of essential items** (parts of the device, 100 ml collection syringes, 60 ml purification syringes and clamping scissors)

- If the device or parts of it are missing – collection is impossible and must be reported to the CBB
- Collection syringes – If there is at least one collection syringe, you can collect, but you must report this to the CBB. If there are no parts, or parts are missing, the umbilical cord blood must be collected in the traditional way (blood donor bags or syringes) provided by the hospital. Report this to the CBB.
- Clamping scissors – If there is at least one pair of scissors, you can continue to collect and use reusable clamping scissors from the hospital for the second clamping. If they are missing, collection is impossible and this must be reported to the CBB.

**Lack of accessories** (non-essential items): These can be replaced by similar hospital supplies.

Problem: **Defects in the kit.**
Solution: **Defective essential items** (Parts of the device, 100 ml collection syringes, 60 ml purification syringes and clamping scissors).

- If the device or parts of it are defective, you must decide on the spot, based on the nature of the defect, whether you can collect. In any case please report on your decision to the CBB.
- Collection syringes – If at least one of them is in working condition, continue to collect and report this to the CBB. If all of the syringes are defective, use the syringes provided by the hospital and transfer as quickly as possible to a blood donor bag from the department stock.
- Clamping scissors – If there is at least one pair of scissors in working order, you can continue to collect and use reusable clamping scissors from the hospital for the second clamping. If there are no scissors at all, collection is impossible and this must be reported to the CBB.

**Defective accessories** (non-essential items): These can be replaced with similar hospital supplies.

Problem: **Contamination of an item in the sterile kit.**
Solution:

- If possible, the item should be replaced with similar hospital supplies.
- An item that cannot be provided by the hospital must be disinfected with 70% alcohol or Povidine.

## *The collection stage*

**Problem:** **Broken device** (clear chamber, filter).
**Solution:**

- A break in the clear chamber that causes detachment of the assembly requires discontinuing of the collection and immediately reporting to the CBB.
- A break in the filter allows you to continue collecting the blood, but the CBB must be informed.

**Problem:** **Blood or solution leaks** during the operation.
**Solution:** You may continue collecting.

**Problem:** **Lack of blood** (for reasons related to insufficient blood in the placenta, delays in collection, limited skill of the collector).
**Solution:** If a small quantity has been collected, send to the CBB laboratory.
If no blood has been collected at all, perform the following actions:

- Try to collect using the traditional bag method (from hospital stock).
- Send it to the CBB laboratory with a report about the problem.

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