Instructions for Use

ProCell®
enhancing patient blood management

REF SBRU-01-CE

Surgical Sponge-Blood Recovery Unit

SUPERCEDED BY REVISION B
AS OF 7/5/23

Indications for Use:

ProCell® facilitates the extraction of blood from surgical sponges as a preliminary step in the process of cell- salvage/intra-operative autotransfusion (IAT).

ProCell® functions as a blood collection device only and does not filter or otherwise process the blood recovered. As an accessory to IAT, it is used in conjunction with standard cell-salvage equipment which must process the blood retrieved from ***Pro***Cell® prior to re-infusion into the patient.

Designed for ease-of-use directly on the surgical instrument table, the disposable ***Pro***Cell® can be used repeatedly during a single patient surgical case and provides an alternative to other sponge-blood recovery methods including handwringing.

Intended Use:

ProCell® is intended for use during surgical procedures where medium to high patient blood loss and surgical sponge use are expected, and the process of cell-salvage/intra-operative autotransfusion (IAT, e.g., Cell Saver) will be used.

The recovery of blood from surgical sponges enhances blood conservation and promotes patient blood management practices.

Intended User:

ProCell® is intended to be used by clinicians/nurses/operating room technicians that handle surgical sponges during surgical procedures.

Features of *Pro*Cell®:

ProCell® has key features and ease of use including the following:

- Sterile disposable medical device
- Up to 50 uses within a single patient case
- Operates on vacuum commonly found and readily available within the operating room (typically 300-500 mmHg)
- Enhances blood conservation and promotes patient blood management practices
- Eliminates the need for manual handwringing of surgical sponges

Contraindications:

There are no known contraindications for the use of the ProCell® medical device. The procedural risk/benefit ratio of blood salvage from surgical sponges must be determined on an individual basis by the surgeons and clinical staff involved in the patient's care. The decision to use this device is based on the decisions made to use IAT for the surgical procedure.

Warnings and Precautions:

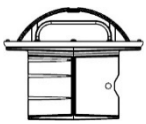
- ProCell® functions as a blood collection device only and does not filter or otherwise process the blood recovered. ProCell® must be used in conjunction with standard IAT cell-salvage equipment (e.g. Cell Saver® manufactured by Haemonetics) which must process the blood retrieved from ProCell® prior to re-infusion into the

patient.

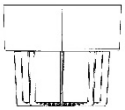
- **Do not re-infuse blood directly from ProCell®!** Reinfusing blood directly from ProCell® into the patient may cause patient injury.
- Do not use the device if any damage or malfunction is observed or encountered (e.g., broken or damaged components, etc.). In these circumstances manual handwringing can be used to extract blood from the surgical sponges.
- Discard and do not use previously opened or damaged devices. Use only devices that are packaged in unopened and undamaged containers.
- FOR SINGLE PATIENT USE ONLY. Reuse may result ln patient infection or injury.
- Do not use if there is loss of sterility of the device. Use of a non-sterile device may result in patient infection or injury.
- Do not re-sterilize. Use of a re-sterilized device may result in patient infection or injury.
- Do not use after expiration date.
- Users of ***Pro***Cell® must take the appropriate precautions when handling blood products and disposing of blood-contaminated material to ensure personal safety as well as the safety of others who may come in contact with the material.
- The ProCell® **medical device is not intended to store blood. As soon as reasonably possible, blood extracted from surgical sponges should be transferred to the IAT cell salvage equipment.**

Instructions for Use:

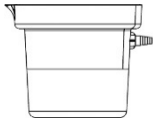
Sterile contents include one fully assembled ***Pro***Cell® consisting of three individual components: lid, sponge basket & reservoir.



Lid



Sponge Basket



Reservoir

Standard wall suction provides the necessary power to activate ***Pro***Cell® and automatically moves the lid downwards. ProCell is connected to wall suction using suction tubing readily available in operating rooms. It is recommended to use a separate sterile vacuum suction tubing line for use with ***Pro***Cell®.

Select a location on the surgical instrument table that allows ***Pro***Cell® to rest on a smooth, flat surface and always remains within easy reach of the operator.

The vacuum suction tubing should be secured adjacent to ***Pro***Cell® using a sterile, non-piercing drape clamp. This will accommodate the repeated attachment and detachment of the vacuum suction tubing onto the vacuum port located on the outside of the ***Pro***Cell® reservoir.

Surgical sponges may be used dry or may be saline saturated (to minimize blood retention in the sponge) and wrung out prior to use for blood collection. Note: The use

of a dry sponge may result in less blood collected due to blood retention in the sponge. ***Pro***Cell® may be used for patients who are heparinized or are not heparinized. Note: Testing of non-heparinized blood has not been conducted.

Cautions:

- The vacuum suction tubing should not be attached to ***Pro***Cell® until the device is ready to activate.
- After activation, the vacuum suction tubing must be detached from ***Pro***Cell® before the lid and basket or the lid alone can physically be removed from the reservoir.

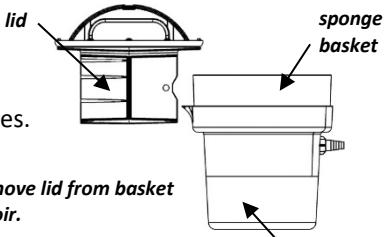
Step 1: Removal of Lid from Basket:

The lid can be removed from the basket with one hand while holding the reservoir and basket with the other hand .

Alternatively, remove the lid and basket as one unit while the other hand supports the reservoir. Then, remove the lid from the basket by lifting and twisting the handle with one hand and holding the lower part of the basket with the other hand.

Place the basket back inside the reservoir.

ProCell® is now ready to accept the saturated sponges.

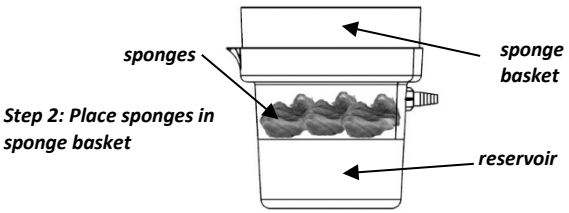


Step 1: Remove lid from basket and reservoir.

Step 2: Placement of Sponges into *Pro*Cell®:

Saturated surgical sponges can now be placed into the open basket.

ProCell® can be activated with a maximum of three saturated 12”x12” surgical sponges.



Step 2: Place sponges in sponge basket

Caution: For proper device operation, ensure all sponges, including the radiopaque markers, are placed completely inside the sponge basket and do not protrude out and over the basket prior to lid insertion. If the lid does not fully seat inside the sponge basket, the blood may not be extracted from the surgical sponges. If this occurs, simply place the sponges with radiopaque markers fully inside the

device and reseat the lid.

If too many sponges are placed inside the sponge basket the lid will not fully seat and the device will not activate. Simply remove a sponge and reseat the lid ensuring the lid can be set into the basket.

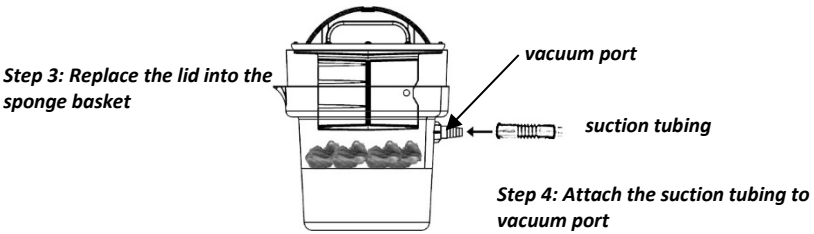
Step 3: Replacement of Lid:

Prior to activating ***Pro***Cell®, the lid must be set into the basket until the lid's lower plate is in light contact with the sponges. Ensure that the upper seal of the lid is fully engaged within the upper end of the basket. It is not necessary to fully compress the sponges.

Step 4: Activation of *Pro*Cell®:

- Prior to activation, ensure that:
- A maximum of three 12" x 12" surgical sponges are inside the basket. Ensure all sponges, including the radiopaque markers, are placed completely inside the sponge basket and do not protrude out prior to lid insertion.
- The lid is properly positioned within the sponge basket
- The unit is resting on a smooth, flat surface.

To begin activation, attach the vacuum suction tubing to the vacuum port on the reservoir. Activation will occur immediately and the lid will begin to move downward into the sponge basket. Ensure that the device remains stable during the initiation of every activation. Under normal operation, blood being recovered will not enter the vacuum port.



Maximum vacuum pressure of the ***Pro***Cell® device is 546mmHg.

Leave the ***Pro***Cell® activated with suction tubing attached to suction port until cessation of blood extraction where very little blood continues to drip from the sponges (approx. 30 - 60 seconds).

Step 5: De-activation:

Before detaching suction, ensure that suction tubing is properly secured to the surgical drape to maintain sterility and convenience during repeated uses.

Detach the vacuum suction from ***Pro***Cell®'s vacuum port.

Step 6: Removal of Lid and Basket to Access the Recovered Blood in Reservoir:

One hand should support the reservoir while the other lifts on the lid handle to remove the lid and basket as one unit.

The lower end of the basket will be slightly wet, it is recommended to place the lid and basket down onto a folded surgical towel or equivalent for absorption.

Step 7: Transfer of Recovered Blood from *Pro*Cell® to the IAT Equipment:

No manipulation of the collected blood is necessary (including removal of any visible clots).

The recovered blood can now be sent to the cell-salvage equipment using the IAT's own suction tip placed directly into the open ***Pro***Cell® reservoir. Tipping ***Pro***Cell® slightly may help facilitate blood flow through the suction tip.

Step 8: Preparing *Pro*Cell® for the Next Activation Cycle:

When not in use, the lid and basket should be returned to the reservoir to await the next placement of saturated sponges into the basket.

ProCell® may be used to process saturated sponges up to 50 times during a single surgical case.

Caution: The ProCell medical device should be disposed of at the conclusion of the surgical procedure and should not be reused on a different patient. The risk remains that if the device is reused for a different patient, there could be cross-patient infection and/or blood incompatibility.

Step 9: Disposal of *Pro*Cell®

At the conclusion of the surgical procedure, the three ***Pro***Cell® components should be handled according to the hospital's own standard operating room protocol regarding disposal of biohazard materials.

Specifications:

- Maximum capacity: 500 mL
- Dimensions: Length (spout to vacuum port): 7.79 in x Width: 6.71 in. x Height: 7.33 in.
- Provided sterile using gamma irradiation
- Not made with natural rubber latex

Reporting Serious Incidents:

Any serious incident that has occurred in relation to the device should be reported to ProCell Surgical Inc. as the manufacturer and the Competent Authority of the Member State in which the user and/or patient is established

Storage and Handling

Keep package dry.

ProCell Surgical Inc.
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Suite 700
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617-849-7900

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UDI ++B890SBRU012V

CE
2862

Symbols

Do not re-use (Note: single patient use)

Do not resterilize

STERILE R Sterilized using irradiation

Do not use if package is damaged

Caution, consult accompanying documents

Expiration date

REF Catalogue number

LOT Batch code

Legal Manufacturer

Date of Manufacture

Consult Instructions for Use

Country of Manufacture

MD Medical Device

Single Barrier System with Protective Packaging Inside

UDI Unique Device Identifier

EC REP Authorized Representative

Consult instruction for use or consult electronic instruction for use
procellsi.com/IFU