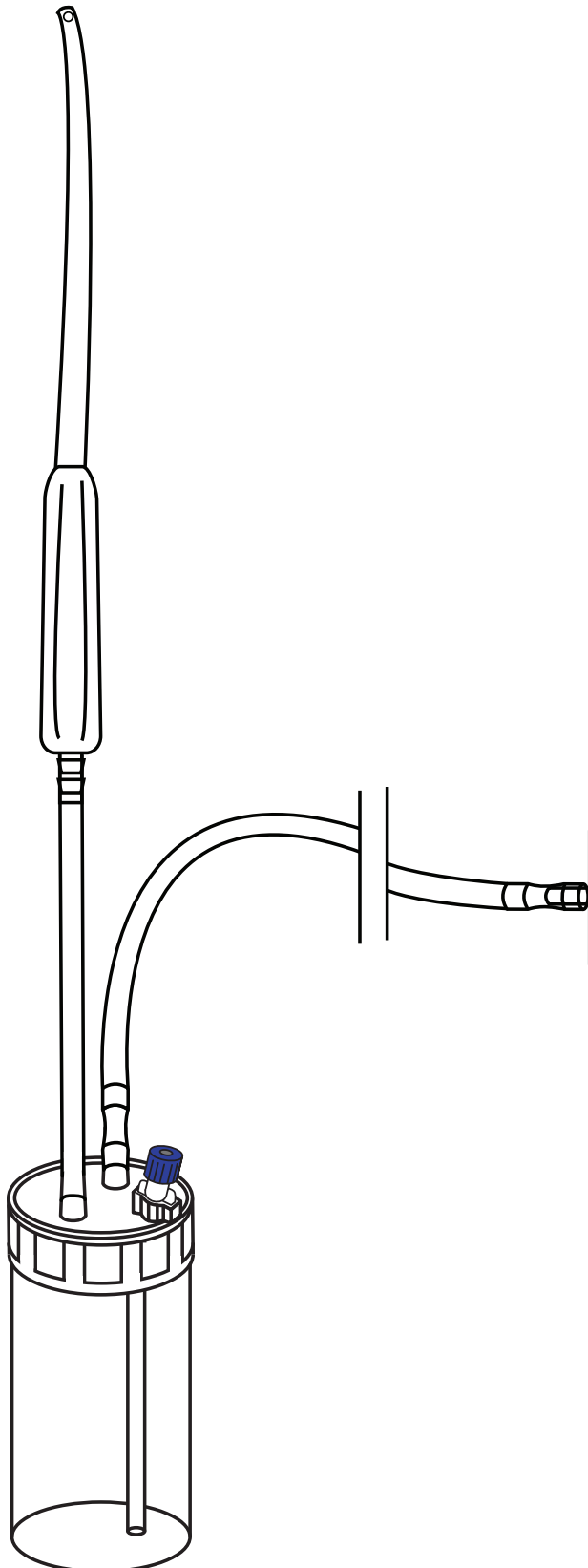


NOT MADE WITH NATURAL RUBBER LATEX



www.cealogic.com



Explanation of symbols on package labeling

	Caution, Consult Accompanying Documents
	Lot Number
	Catalog Number
	Sterilized Using Ethylene Oxide
	Do Not Reuse
	Use By
	Open Here
	Fragile, Handle With Care
	This Way Up

INTRODUCTION

The Recibio, Inc. CeaLogic™ Specimen Collection Kit consists of SINGLE USE components to be used solely for the assembly of the CeaLogic™ Specimen Collection Kit.

Indications for Use

The Recibio, Inc. CeaLogic™ Specimen Collection Kit is intended for use of normal suction and specimen collection.

Description

The Recibio, Inc. CeaLogic™ Specimen Collection Kit is intended for specimen collection as deemed necessary by the surgeon’s determination of the clinical use requirements to facilitate specimen collection.

Warnings

SINGLE USE, Resterilizing or re-use may compromise the structural integrity of the device, its components and lead to device failure. Reuse of this single patient device creates a risk of patient and user infections. Contamination of the device may lead to injury, illness or possibly death of the patient and user.

Cautions

NON-PYROGENIC DEVICE

FEDERAL LAW (USA) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

DO NOT RE-STERILIZE.

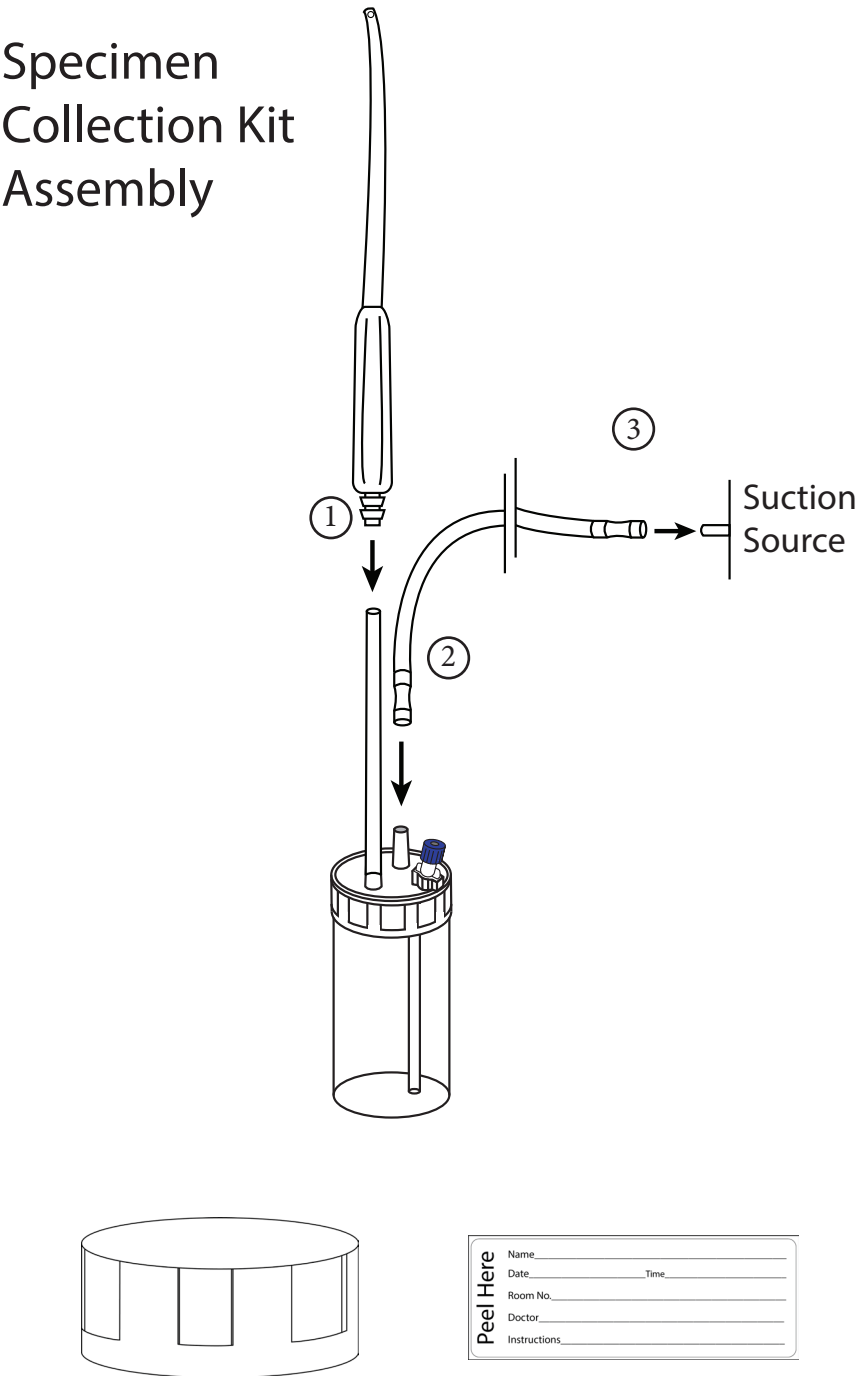
Instructions

Note: Using aseptic technique, remove components of the CeaLogic™ Specimen Collection Kit from the sterile package.

- ①. Connect Yankauer Suction Catheter to latex-free inlet tubing.
- ②. Connect end of supplied or additional 3/8 inch suction tubing to open port.
- ③. Connect opposite end of suction tubing to normal suction source.

Additional Instructions:

- Use CeaLogic™ Specimen Collection Kit to collect specimen based on surgeon's determination of clinical use requirement.
 - Specimen Container Lid and Label are included for use by physician should sterile sample need to be transported. To use, remove the lid from the Specimen Collection Container and affix Specimen Container Lid and Specimen Container Label.
 - Be certain to remove blue cap prior to connecting a sterile Luer-Lok™ syringe for sterile specimen removal.
-



Recibio, Inc. CeaLogic™ Specimen Collection Kit Limited Warranty¹ (USA)

THE FOLLOWING LIMITED WARRANTY APPLIES TO UNITED STATES CUSTOMERS ONLY:

- This Limited Warranty provides the following assurance to the customer who receives the Recibio, Inc. CeaLogic™ Specimen Collection Kit, hereafter referred to as the “Product”.
 - Should the product fail to function within normal tolerances due to a defect in materials or workmanship prior to its “Use before Date” Recibio Inc., will at its option (1) issue a credit equal to the purchase price, as defined in Section 1 (B), against the purchase of the replacement product or (2) provide a functionally comparable replacement at no charge.
 - As used herein, Purchase Price shall mean the lesser of the net invoiced price of the original, or current functionally comparable, or replacement.
- To qualify for the limited warranty, these following conditions must be met.
 - The product must be used prior to expiration and/or before its “use by date”
 - The unused, non-contaminated portion of the CeaLogic™ Specimen Collection Kit must be returned to Recibio, Inc. within 30 days of use and shall be come property of Recibio, Inc..
 - The product must not have been altered, subject to improper assembly, misuse, abuse, or accident.
 - The product may not have been used by any other customer other than the purchaser or a representative of the purchaser.
- This Limited Warranty is limited to its express terms. In exact:
 - Except as expressly provided by this Limited Warranty, RECIBIO, Inc. IS NOT RESPONSIBLE FOR ANY DIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES BASED ON ANY DEFECT, FAILUER OR Malfucntion of the product, whether the claim is based on warranty, contract, tort, or otherwise.
 - This Limited Warranty is made only to the customer in whom the product is used. AS TO ALL OTHERS, RECIBIO, INC. MAKES NO WARRANTY, EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO, ANY IMPLIE WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE WHETHER ARISING FROM STATUTE, COMMON LAW, CUSTOMOR OTHERWISE. NO EXPRESS OR IMPLIED WARRANTY TO THE CUSTOMER SHALL EXTEND BEYOND THE PERIOD SPECIFIED IN 1(A.) ABOVE. THIS LIMITED WARRANTY SHALL BE THE EXCLUDE REMEDY AVAILABLE TO ANY PURCHASER, AS DESCRIBED ABOVE.
 - The exclusions and limitations set out above are not intended to, and should not be construed so as to contravene mandatory provisions of the applicable law. If any part or term of this Limited Warranty is held to be illegal, unenforceable or in conflict with applicable law by a court of a competent jurisdiction, the validity of the remaining portions of the Limited Warranty shall not be affected, and all rights and obligations shall be construed and enforced as if this Limited Warranty did not contain the particular part or term held to be invalid. This Limited Warranty gives the purchaser specific legal rights. The purchaser may have other rights which vary from state to state.
 - No person has any authority to bind Recibio, Inc to any representation, condition or warranty except this Limited Warranty.

¹ This Limited Warranty is provided by Recibio, Inc. 1860 FM 359 #171, Richmond TX 77406, USA. It applies only to the United States of America. Areas outside of the United States should contact their local The Recibio, Inc. CeaLogic™ Specimen Collection Kit representative for the exact terms of the Limited Warranty.

Recibio, Inc. CeaLogic™ Specimen Collection Kit Limited Warranty¹(OUTSIDE USA)

THE FOLLOWING LIMITED WARRANTY APPLIES TO ALL CUSTOMERS OUTSIDE THE UNITED STATES OF AMERICA.

- This LIMITED WARRANTY provides assurance for the customer who receives a Recibio, Inc. CeaLogic™ Specimen Collection Kit (“Product”) that should the product fail to function to specification, Recibio, Inc. will issue a credit equal to the original purchase price(but not exceed the value of a replacement product) against the purchase of any replacement product used for that customer. THE WARNINGS CONTAINED IN THE PRODUCT LABELING ARE CONSIDERED AN INTEGRAL PART OF THIS LIMITED WARRANTY. Contact your local Recibio, Inc. representative to obtain information on how to process a Limited Warranty claim.
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 - The unused, non-contaminated portion of the CeaLogic™ Specimen Collection Kit must be returned to Recibio, Inc. within 30 days of use and shall be property of Recibio, Inc..
 - The product must not have been altered, subject to improper assembly, misuse, abuse, or accident.
 - The product must not have been used more than one time for any customer.
- This LIMITED WARRANTY is limited to its express terms. In particular:
 - In no event shall any replacement credit be granted where there is evidence of improper handling, improper use or material alteration of initial or replaced product.
 - Recibio, Inc. is not responsible for any direct, incidental or consequential damages based on any defect, failure or malfunction of the product, whether the claim is based on warranty, contract, tort, or otherwise.
- This LIMITED WARRANTY does not cover those parts that, by their nature, Recibio, Inc. considers used outside standard assembly and use.
- The exclusions and limitations set out above are not intended to, and should not be construed so as to contravene mandatory provisions of the applicable law. If any part or term of this Limited Warranty is held to be illegal, unenforceable or in conflict with applicable law by a court of a competent jurisdiction, the validity of the remaining portions of the Limited Warranty shall not be affected, and all rights and obligations shall be construed and enforced as if this Limited Warranty did not contain the particular part or term held to be invalid.
- No representative, agent, dealer, retailer, or intermediary of Recibio, Inc. shall have the authorization to amend the contents of this LIMITED WARRANTY.
- The validity, interpretation and performance of the agreement for which this LIMITED WARRANTY is issued, as well as any disputes relating to or connected thereto is controlled by and construed under the laws of the State of Texas, USA.

Components

All components are shipped sterile in package.

The Recibio, Inc. CeaLogic™ Specimen Collection Kit consists of the following components:

- One (1) Specimen Collection Container
 - One (1) 10' - 1/4" Suction Tubing with Male Adapter
 - One (1) Yankauer Suction Tip
 - One (1) Specimen Cap
 - One (1) Specimen Label
 - One (1) Product Sticker Sheet
 - One (1) Assembly Diagram/Information Booklet
 - One (1) Extension Set
 - One (1) 5 in 1 Connector
-

⚠ WARNING: Due to sterilization, this product can expose you to Ethylene Oxide, known to the State of California to cause cancer and/or birth defects or other reproductive harm. For more information, go to www.P65Warnings.ca.gov

www.cealogic.com

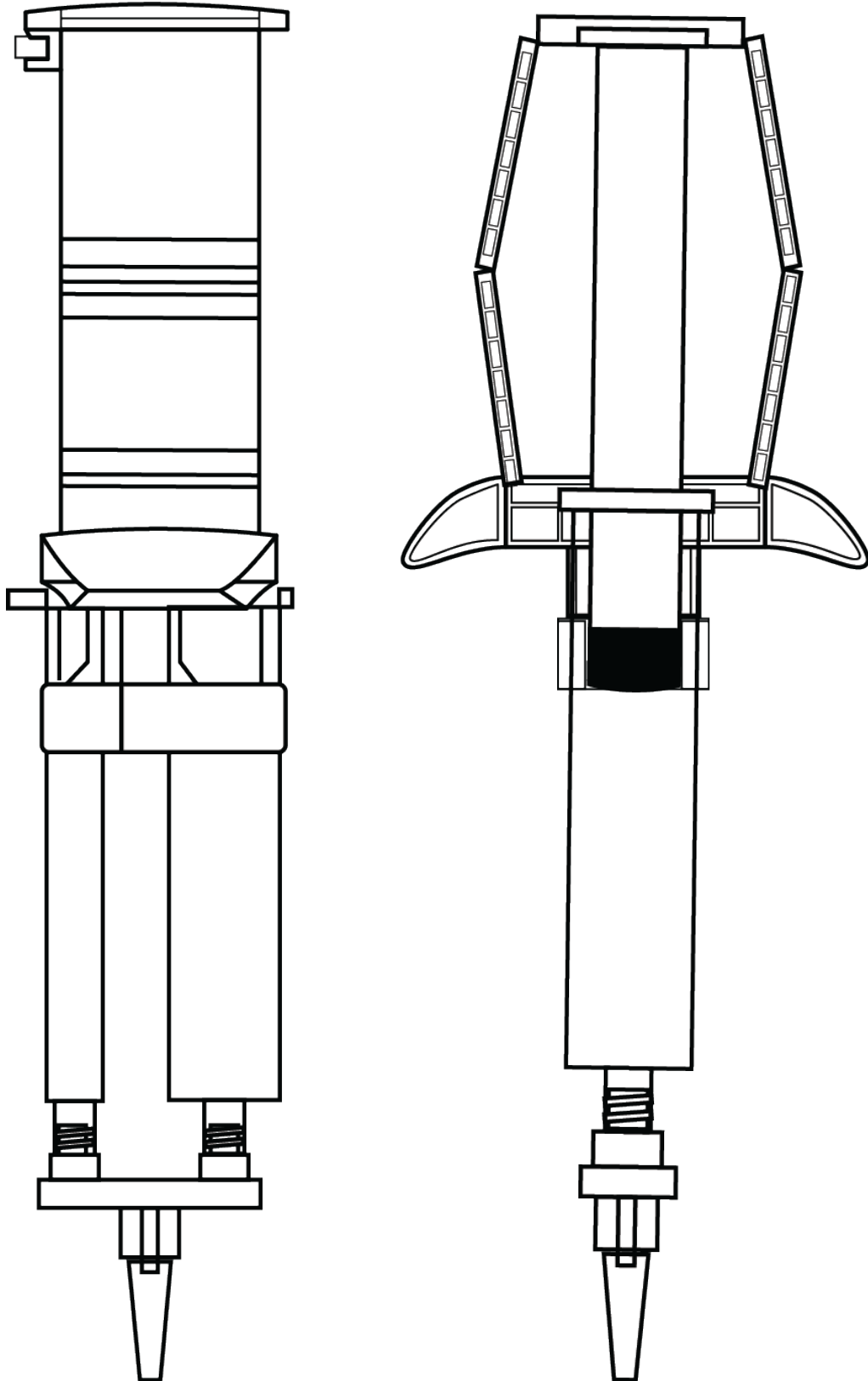


1860 FM 359 #171
Richmond, TX 77406 USA
www.recibio.us

Toll free USA 1-844-732-4246

Made in the U.S.A. including foreign components
Assembled by Busse Hospital Disposables

Not made with natural rubber latex



www.cealogic.com



Explanation of symbols on package labeling

	Caution, Consult Accompanying Documents
	Lot Number
	Catalog Number
	Sterilized Using Ethylene Oxide
	Do Not Reuse
	Use By
	Open Here
	Fragile, Handle With Care
	This Way Up

INTRODUCTION

The Recibio, Inc. CeaLogic™ Ratio Applicator Kit consists of SINGLE USE components to be used solely for the assembly of the CeaLogic™ Ratio Applicator.

Indications for Use

The CeaLogic Ratio Applicator Kit is indicated for use in applying two non-homogeneous fluids to a treatment site.

Description

The Recibio, Inc. CeaLogic™ Ratio Applicator Kit is intended for the application of fluids as deemed necessary by the surgeon’s determination of the clinical use requirements to facilitate the preparation of the treatment site.

Contraindications

The CeaLogic ratio Applicator is contra-indicated for intravascular use.

Warnings

When using two dissimilar fluids, compatibility, appropriateness, and possible interaction must be evaluated. Refer to the surgical fluid, anti-biotic, or other fluid Instructions for Use provided with the fluid to be applied.

Dosage and Method

Dosage is dependent upon procedure and surgeon’s determination. Maximum fluid viscosity of 30 cp for use with Luer Spray Tip. To obtain even coverage, keep constant pressure on the dispenser and spray with a sweeping motion.

Cautions

NON-PYROGENIC DEVICE

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DO NOT RE-STERILIZE.

Pre-Assembly Instructions

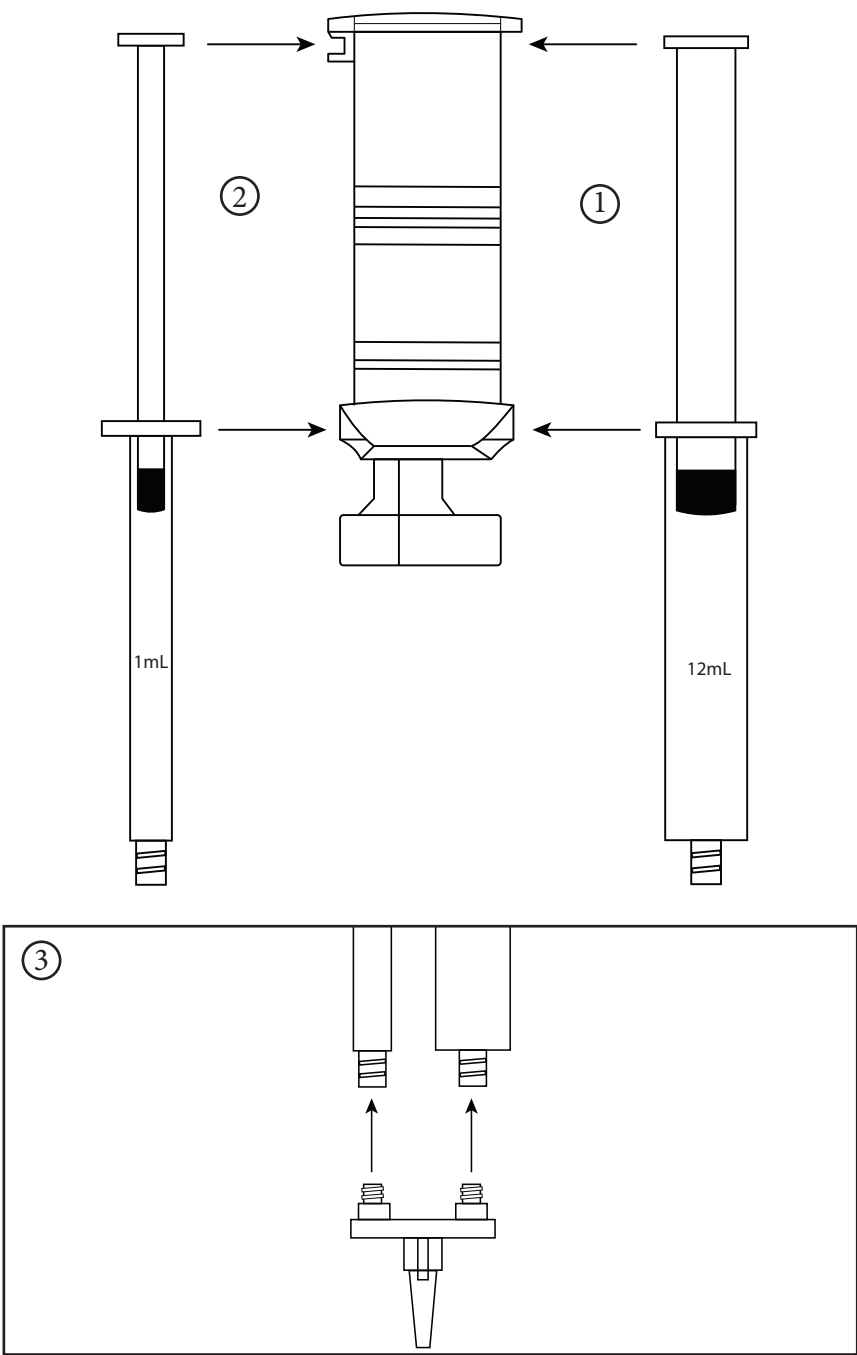
- Using aseptic technique, remove components of the CeaLogic™ Ratio Applicator Kit from the sterile package.
- Fill the larger 12-mL syringe with desired fluid.
- Fill the smaller 1-mL syringe with the second fluid at approximately the same level. The proportions of fluid in the two syringes should be comparable.

Final Assembly Instructions

- ① Click the 12-mL syringe into the larger side of the Dispenser. The syringe should snap into the Dispenser at both the plunger and the waist.
- ② Click the 1-mL syringe into the smaller side of the Dispenser. The syringe should snap into the Dispenser at both the plunger and the waist.
- ③ Connect the Spray Tip with Dual-Lock Adapter to the 12-mL syringe and 1-mL syringe simultaneously and tighten.

NOTE: Depress Dispenser to apply fluids in combination onto desired site.

Ratio Applicator Assembly



Recibio, Inc. CeaLogic™ Ratio Applicator Kit Limited Warranty¹ (USA)

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 - Should the product fail to function within normal tolerances due to a defect in materials or workmanship prior to its “Use before Date” Recibio Inc., will at its option (1) issue a credit equal to the purchase price, as defined in Section 1 (B), against the purchase of the replacement product or (2) provide a functionally comparable replacement at no charge.
 - As used herein, Purchase Price shall mean the lesser of the net invoiced price of the original, or current functionally comparable, or replacement.
- To qualify for the limited warranty, these following conditions must be met.
 - The product must be used prior to expiration and/or before its “use by date”
 - The unused, non-contaminated portion of the CeaLogic™ Ratio Applicator Kit must be returned to Recibio, Inc. within 30 days of use and shall be come property of Recibio, Inc..
 - The product must not have been altered, subject to improper assembly, misuse, abuse, or accident.
 - The product may not have been used by any other customer other than the purchaser or a representative of the purchaser.
- This Limited Warranty is limited to its express terms. In exact:
 - Except as expressly provided by this Limited Warranty, RECIBIO, Inc. IS NOT RESPONSIBLE FOR ANY DIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES BASED ON ANY DEFECT, FAILUER OR Malfucntion of the product, whether the claim is based on warranty, contract, tort, or otherwise.
 - This Limited Warranty is made only to the customer in whom the product is used. AS TO ALL OTHERS, RECIBIO, INC. MAKES NO WARRANTY, EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO, ANY IMPLIE WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE WHETHER ARISING FROM STATUTE, COMMON LAW, CUSTOMOR OTHERWISE. NO EXPRESS OR IMPLIED WARRANTY TO THE CUSTOMER SHALL EXTEND BEYOND THE PERIOD SPECIFIED IN 1(A.) ABOVE. THIS LIMITED WARRANTY SHALL BE THE EXCLUDE REMEDY AVAILABLE TO ANY PURCHASER, AS DESCRIBED ABOVE.
 - The exclusions and limitations set out above are not intended to, and should not be construed so as to contravene mandatory provisions of the applicable law. If any part or term of this Limited Warranty is held to be illegal, unenforceable or in conflict with applicable law by a court of a competent jurisdiction, the validity of the remaining portions of the Limited Warranty shall not be affected, and all rights and obligations shall be construed and enforced as if this Limited Warranty did not contain the particular part or term held to be invalid. This Limited Warranty gives the purchaser specific legal rights. The purchaser may have other rights which vary from state to state.
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Recibio, Inc. CeaLogic™ Specimen Collection Kit Limited Warranty¹(OUTSIDE USA)

THE FOLLOWING LIMITED WARRANTY APPLIES TO ALL CUSTOMERS OUTSIDE THE UNITEDSTATES OF AMERICA.

- This LIMITED WARRANTY provides assurance for the customer who receives a Recibio, Inc. CeaLogic™ Ratio Applicator Kit (“Product”) that should the product fail to function to specification, Recibio, Inc. will issue a credit equal to the original purchase price(but not exceed the value of a replacement product) against the purchase of any replacement product used for that customer. THE WARNINGS CONTAINED IN THE PRODUCT LABELING ARE CONSIDERED AN INTEGRAL PART OF THIS LIMITED WARRANTY. Contact your local Recibio, Inc. representative to obtain information on how to process a Limited Warranty claim.
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- This LIMITED WARRANTY is limited to its express terms. In particular:
 - In no event shall any replacement credit be granted where there is evidence of improper handling, improper use or material alteration of initial or replaced product.
 - Recibio, Inc. is not responsible for any direct, incidental or consequential damages based on any defect, failure or malfunction of the product, whether the claim is based on warranty, contract, tort, or otherwise.
- This LIMITED WARRANTY does not cover those parts that, by their nature, Recibio, Inc. considers used outside standard assembly and use.
- The exclusions and limitations set out above are not intended to, and should not be construed so as to contravene mandatory provisions of the applicable law. If any part or term of this Limited Warranty is held to be illegal, unenforceable or in conflict with applicable law by a court of a competent jurisdiction, the validity of the remaining portions of the Limited Warranty shall not be affected, and all rights and obligations shall be construed and enforced as if this Limited Warranty did not contain the particular part or term held to be invalid.
- No representative, agent, dealer, retailer, or intermediary of Recibio, Inc. shall have the authorization to amend the contents of this LIMITED WARRANTY.
- The validity, interpretation and performance of the agreement for which this LIMITED WARRANTY is issued, as well as any disputes relating to or connected thereto is controlled by and construed under the laws of the State of Texas, USA.

Kit Components

All components are shipped sterile in package.

The Recibio, Inc. CeaLogic™ Ratio Applicator Kit consists of the following components:

- One (1) Sterile Peel Pack containing all components
- One (1) 12-ml syringe
- One (1) 1-ml syringe
- One (1) Dispenser
- One (1) Dual Lock Adapter
- One (1) Spray Tip
- One (1) Specimen Container
- One (1) Specimen Container Lid

⚠ WARNING: Due to sterilization, this product can expose you to Ethylene Oxide, known to the State of California to cause cancer and/or birth defects or other reproductive harm. For more information, go to www.P65Warnings.ca.gov



1860 FM 359 #171
Richmond, TX 77406 USA
www.recibio.us

Toll free USA 1-844-732-4246

Made in the U.S.A. including foreign components
Assembled by Busse Hospital Disposables





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US[REDACTED] Recibio, Inc.
1860 FM 359 #171, Richmond, TX 77406
Phone: 1-844-798-4846
www.cealogic.com

 Foshan United Medical Technologies Ltd.
No. 1 Huixing Road, Yanbu, Dali, Nanhai, Foshan, Guangdong
Province, 528247, China www.umtmedical.com

 **CealLogic™ RIBBON**
Chitosan Absorbent Gelling Fiber Dressing

REF NO. 9356



Product Description

CeaLogic™ Ribbon is a soft, sterile, absorbent fibre wound dressing made from Chitosan. Chitosan is known for its bacteriostatic and haemostatic properties. CeaLogic™ Ribbon is highly absorbent, conformable and transforms into a soft gel upon absorption of wound exudate. CeaLogic™ Ribbon helps maintain a moist environment for optimal wound healing, conforming closely to the wound bed for optimal interaction. The dressing can aid autolytic debridement and will remain intact during use (one-piece removal). CeaLogic™ Ribbon will not damage newly formed tissue.

Indications

CeaLogic™ Ribbon is indicated for the management of moderate to heavily exuding chronic and acute wounds. CeaLogic™ Ribbon may be used to control minor bleeding in superficial wounds. CeaLogic™ Ribbon can be used on infected wounds or wounds in which there is an increased risk of infection under the supervision of medical professionals. Under medical supervision CeaLogic™ Ribbon may be used for the management of the following wounds:

- Pressure sores
- Venous ulcers
- Diabetic ulcers
- Leg ulcers
- Cavity wounds
- Donor sites and Graft sites
- Surgical wounds (e.g. post-operative, wounds left to heal by secondary intent)
- Skin abrasions and lacerations
- Superficial and partial thickness burns
- Trauma Wounds

Contra-indications

The CeaLogic™ Ribbon is not indicated for use on the following:

- Surgical implantation
- To control heavy bleeding
- Individuals who are sensitive, or who have had an allergic reaction, to the dressing.
- 3rd degree burns

Directions for use

Site Preparation

Debride when necessary and irrigate/clean the wound site in accordance with standard protocols.

Dressing Selection

For flat or shallow wounds select an appropriate size dressing that allows for a minimum of 0.5 cm overlap onto the skin surrounding the wound (to allow for the dressing to gel and to maximise conformability). Use a ribbon (rope) dressing for cavity wounds."

Dressing Application

1. Always use aseptic techniques when dressing a wound
2. Cut, fold or layer, the dressing to fit the wound
3. Loosely fill deep wounds, to allow the CeaLogic™ Ribbon to absorb wound fluid and to expand filling the wound. Do not pack tightly.
4. When using CeaLogic™ Ribbon ribbon dressings in deep cavity wounds, insert the ribbon in one piece and leave at least 2.5cm outside the wound for ease of removal
5. Cover and secure with an appropriate secondary dressing
6. For dry wounds (to aid a moist wound environment) place a CeaLogic™ Ribbon on the wound and wet with sterile fluid or saline over the wound area only. Cover the dressing with an occlusive or semi-occlusive dressing to maintain moisture at the wound site and to avoid subsequent dressing adherence to the wound
7. For minor bleeding wounds, apply the CeaLogic™ Ribbon to the wound with a light pressure, maintain the pressure for few minutes until the bleeding is stopped, secure the dressing with a suitable secondary dressing

Dressing Change and Removal

1. CeaLogic™ Ribbon shall be changed when the dressing has reached it's absorption capacity, or when the conditions of the wound or the surrounding skin are the level of exudate requires.
2. If simple removal of the dressing is difficult due to adherence, it should be fully saturated with sterile saline or sterile water to fully gel the dressing, remove slowly
3. Irrigate the wound site with a suitable wound cleanser (e.g. sterile saline) prior to application of a new dressing

Storage

Store in a cool, dry place.

Do not re-sterilise

The use by date of this product is printed on the packaging.

SYMBOLS USED ON LABELLING



Single use



Do not Re-sterilise



Use by: year and month.



Sterile. Method of sterilisation: EO



Product Reference



Batch number.



Attention, see instructions for use.



Does not contain Latex



Storage Conditions



Manufacturer



Representative



Date of manufacture



Keep Away from Sunlight



Keep Dry



Do not use if package is open or damaged



Medical Device



See instruction for use



Single sterile barrier system

GTIN

Global Trade Item Number



Unique device identifier



⚠ WARNING: Due to sterilization, this product can expose you to Ethylene Oxide, known to the State of California to cause cancer and/or birth defects or other reproductive harm. For more information, go to www.P65Warnings.ca.gov



USREP Recibio, Inc.
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Phone: 1-844-798-4846
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 Foshan United Medical Technologies Ltd.
No. 1 Huixing Road, Yanbu, Dali, Nanhai, Foshan, Guangdong
Province, 528247, China www.umatmedical.com

 **CeaLogic™ FILM**
Transparent PU Film Dressing - Frame Style

REF NO. 9357



Product Description

CeaLogic™ Film Dressing consists of a thin film backing with a non-latex, hypoallergenic Adhesive. The dressing is transparent, allowing continual site observation. It is waterproof and impermeable to liquids and bacteria. CeaLogic™ Film Dressing is individually packed and terminally sterilized.

Patient Target Group

Any patient who presents with an appropriate wound type.

Indications

CeaLogic™ Film Dressing can be used as a securement for IV catheter or wound dressing, to cover and protect catheter sites and wounds, as a secondary dressing, as a protective cover over at-risk skin, to secure other devices to the skin. Do not use the dressing as a replacement for sutures and other primary wound closure methods.

Warnings

- CeaLogic™ Film Dressing should not be placed over infected wounds.
- Do not insert the needle through the dressing
- Ensure patient is not sensitive or allergic to adhesive products prior to application.
- If infection is suspected, remove the dressing, inspect the catheter site directly, and determine appropriate medical intervention.
- For external use only.
- Do not use if individual pouch is open or damaged.
- Do not reuse, reuse may cause serious infection.

Precautions

- Do not stretch the dressing during application as tension can cause skin trauma.
- Make sure the skin is clean, free of soap residue and lotion and allowed to dry thoroughly before applying the dressing to prevent skin irritation and to ensure good adhesion
- Choose a dressing size that will adequately cover the insertion site and the catheter. At each dressing change, pay careful attention to disinfecting the skin around and under the character.
- CeaLogic™ Film Dressing should not be re-sterilized.

Application

1. Prepare the wound site according to institution protocol. Allow all cleansing solutions and skin protectants to dry completely. Take CeaLogic™ Film Dressing out from the package.
2. Peel liner from dressing, exposing adhesive surface. NOTE: For CeaLogic™ Film Dressing Frame Style, remove and discard the latter liner before touching skin.
3. Center the transparent portion of the dressing over the site. Apply firm pressure to entire dressing starting in the center to the edges to enhance adhesion. NOTE: Remove the remaining liner of CeaLogic™ Film Dressing Frame Style and smooth the dressing from the center outward to enhance adhesion. Do not stretch the dressing during application.
4. For CeaLogic™ Film Dressing Frame Style, slowly remove frame while smoothing down dressing edges with your fingertips.
5. For CeaLogic™ Film Dressing Frame Style, slowly remove PE/PET film while smoothing down dressing edges with your fingertips.
6. Smooth the dressing from the center towards the edges, using firm pressure to enhance adhesion.
7. Record information on label, then remove it from liner and place on dressing.

Removal

1. Remove any tape strips applied to the top of the dressing.
2. Using a low and slow removal technique, start removing the dressing from corner. Avoid skin trauma by peeling the dressing back, rather than pulling it up from the skin.
3. Support the skin with your fingers while removing the dressing

Disposable

The dressing should be disposed of in accordance with local waste guidelines.

Storage

Protect from freezing, avoid excessive heat.

SYMBOLS USED ON LABELLING



Single use



Do not Re-sterilize



Use by: year and month.



Sterile. Method of sterilisation: EO



Product Reference



Batch number.



Attention, see instructions for use.



Does not contain Latex



Storage Conditions



Manufacturer



Representative



Date of manufacture



Keep Away from Sunlight



Keep Dry



Do not use if package is open or damaged



Medical Device



See instruction for use



Single sterile barrier system



Global Trade Item Number



Unique device identifier