BLEScath™ Intratracheal Catheter Unabridged FAQs

What is BLEScath?

BLEScath™, with its integrated stainless steel (SS) stylet, is uniquely designed to be compatible with low viscosity surfactants like bovine lipid extract surfactant suspension. BLEScath™ is a 5 Fr radiopaque polyvinyl chloride (PVC) tube with a length of 205 mm and an inner diameter of 0.91 mm with a slip tip connector at the proximal end and a soft rounded tip at the distal end. The integrated SS stylet is rigid but flexible for ease of insertion. Markings on the outside of the catheter aid in determining insertion depth[3].

What is BLEScath™ used for?

BLEScath™ is intended for the administration of bovine lipid extract surfactant suspension using minimally invasive surfactant therapy (MIST)/ less invasive surfactant administration (LISA) technique for rescue treatment of infants with Neonatal Respiratory Distress Syndrome (NRDS)[3]. For exogenous surfactant delivery to the neonate at ≥ 28 weeks and or ≥ 1000 grams, who DOES NOT require intubation or mechanical ventilation and meets the criteria for surfactant administration (i.e. oxygenation requirement met)[3].

Are there any warnings associated with the use of BLES® and BLEScath™?

The use of BLEScath™ and bovine lipid extract surfactant suspension should be restricted to a highly supervised clinical setting with immediate availability of experienced neonatologists and other clinicians experienced with general care of premature infants. Transient episodes of bradycardia and decreased oxygen saturation may occur during dosing[3].

Are there contraindications involved in using BLEScath™?

The use of BLEScath™ and bovine lipid extract surfactant suspension are contraindicated in infants with active pulmonary hemorrhage[3]. Do NOT use BLEScath™ to administer any surfactant other than bovine lipid extract surfactant suspension[3]. BLEScath™ is intended for intratracheal use only. Do NOT introduce BLEScath™ into other body openings[3].

Can I use BLEScath™ with the LISA / MIST Methods?

Yes! BLEScath™ is intended for the administration of bovine lipid extract surfactant suspension using minimally invasive surfactant therapy (MIST) / less invasive surfactant administration (LISA) technique for rescue treatment of infants with Neonatal Respiratory Distress Syndrome (NRDS)[3].

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What is LISA/MIST?

The Less Invasive Surfactant Administration (LISA) or Minimally Invasive Surfactant Therapy (MIST) method uses a small diameter catheter inserted into the trachea to deliver exogenous pulmonary surfactant to a spontaneously breathing patient supported with continuous positive airway pressure (nCPAP).LISA is intended for neonates ≥ 28 weeks and or ≥ 1000 grams. For non-spontaneous breathing patients, please switch to the intubate-surfactant-extubate (INSURE)technique[1,2].

How does LISA compare to INSURE?

- LISA reduces the necessity for intubation and mechanical ventilation[5,6].
- LISA's simplified, fast approach may lead to less hypothermia, oxygen consumption, and stress, ultimately improving respiratory status[4,5].
- LISA's smaller catheter allows the flow of gas through the vocal cords while maintaining the physiological function of the larynx[6].
- With LISA, long-term follow-ups report better pulmonary function and neurocognitive outcomes[4].
- LISA may offer institutions cost savings by decreasing the need for ventilation, consumables, diagnostic procedures, and investigations[4].

When would I use LISA over INSURE?

If the neonate is suffering from NRDS and is spontaneously breathing, the LISA method can be used. LISA is intended for neonates ≥ 28 weeks and or ≥ 1000 grams. For non-spontaneous breathing patients, please switch to the intubate-surfactant-extubate (INSURE) technique[2].

How many times can I try the LISA method before switching to INSURE?

If unable to deliver the dose successfully using MIST/LISA after three attempts, administer the dose via the INSURE method[3].

Do you require a prescription to buy BLEScath™?

You do not need a prescription for BLEScath™.

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What should I consider before inserting BLEScath™?

Use of BLES® and BLEScath™ should be restricted to a highly supervised clinical setting with immediate availability of experienced neonatologists and other clinicians experienced with intubation, ventilator management, and general care of premature infants[3].

BLEScath™ is intended to deliver exogenous pulmonary surfactant to a spontaneously breathing patient supported with continuous positive airway pressure (nCPAP) for neonates ≥ 28 weeks and or ≥ 1000 grams[1,2]. For non-spontaneous breathing patients, please switch tothe intubate-surfactant-extubate (INSURE) technique[2].

Can I use BLEScath™ with any surfactant?

BLEScath™ is indicated to be used only with the surfactant BLES®[3].

BLES® has a relatively low viscosity formulation and has been tested to pass through the small holes in the stylet's anchor at the proximal end of BLEScath™. Other surfactants have not been tested with BLEScath™[3].

What size catheter should I use?

BLEScath™ only comes in one size, 5Fr(1.67mm).

What is the French catheter scale?

The French size is three times the diameter in millimeters. Thus, the French size is roughly equivalent to the circumference of a circular catheter; 1 mm= 3 Fr, 1 Fr = 1/3 mm.

What length of BLEScath™ should I use?

BLEScath™ comes in a length of 205 mm.

Why is the tip of the BLEScath™ round?

BLEScath™'s soft, rounded, distal tip may reduce tracheal tissue injury commonly associated with straight, stiff, or minimally curved catheters[3,4].

Why does the BLEScath™ have only one hole at the distal tip?

The distal markings of 2, 2.5, 3.5 cm and a single hole design decrease unilateral surfactant disposition which will help facilitate the surfactant penetration distally for more rapid spreading and may reduce reflux[5].

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What is the purpose of the cap at the proximal end of the BLEScath™?

The initial design of the catheter includes a cap; however, its presence does not impact the function or purpose. You may remove the cap before the procedure if preferred.

Do I need to freeze BLEScath™ before using it to make it firm?

BLEScath™ DOES NOT need to be frozen before use as the integrated stainless steel (SS) stylet is uniquely designed to make it rigid but flexible for ease of insertion[3].

Do I need to premedicate the neonate with an anesthetic agent before inserting the catheter?

Premedication therapy may differ among institutions. Please refer to your hospital's NICU guidelines regarding using these agents.

Should I use a video laryngoscopy or a conventional laryngoscope?

The choice is yours, depending on the familiarity of use and equipment available in your NICU practice setting.

Do I have to insert the stylet before use or remove it after BLEScath™ is inserted in the patient?

The stainless steel stylet is integrated into the catheter; therefore, it does not require insertion or removal at any time during the procedure[1].

Is there a recommended shape that I should bend the catheter into?

The patient's anatomy is the most significant factor in how the catheter's shape is bent. More anterior curvature is required if the patient has very anterior vocal cords. User personal preference also plays a role in the desired shape as well. Common profiles include a gently "curved," "straight", or "hockey" stick.

How would you recommend that I hold the catheter during the procedure?

Please use either the two-finger or three-finger method (Refer to the Animation Training Video) as guidance for device control.

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How do I know if I placed the BLEScath™ correctly?

There are three unlabelled black line markings near the distal tip (at 2.0, 2.5, and 3.5 cm from the end), which serve as a visual aid for controlling the insertion depth at the level of the vocal cords[3].
Additionally, there are five-line markings of 7 to 11 cm (labeled 7, 8, 9,10, and 11) on the catheter to indicate the distance from the distal tip to the patient's lip (tip to lip distance). The depth of insertion is 6 cm plus birth weight in kilograms[3]. For example: The depth of insertion for a 1 kg baby is 6 cm + 1 = 7 cm.

Is there a simple way to calculate how far to insert the catheter?

The depth of insertion is 6 cm plus birth weight in kilograms.

For example: The depth of insertion for a 1 kg baby is 6 cm + 1 = 7 cm.

What do the three black lines at the distal end of the catheter represent?

The three unlabelled black lines are at 2.0, 2.5, and 3.5 cm from the distal end of the catheter[3].

How long does it take to instill the whole BLES® dose through the BLEScath™?

Instill surfactant in micro-boluses synchronizing with the neonate's inspiration. Micro-bolusing every 2-3 breaths is also acceptable if the infant is tachypneic[3]. It can take 1 to 3 minutes to administer the total dose.

When can I remove the BLEScath™ from the trachea?

When the surfactant installation is complete, inject air through the catheter to empty the syringe and remove the catheter immediately[3].

Can I reuse BLEScath™?

BLEScath™ is intended for single use. Do NOT reuse the catheter[3].

What is BLEScath™ made of[1,3]?

Latex Free, DEHP Free, Stainless Steel, Radiopaque polyvinyl chloride (PVC).

What is DEHP?

DEHP is a chemical softening agent used in many plastic and PVC vinyl products. Some data have shown that DEHP could potentially link to health issues.

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What are the BLEScath™ maintenance best practices?

Store sterile BLEScath™ package at room temperature.

DO NOT use BLEScath™ if the packaging is open or if its contents are damaged[3].

How should I dispose of the BLEScath™?

Please follow your hospital's biomedical waste disposal policy.

What should I do to prevent the introduction of infections to the neonate?

BLEScath™, when packaged, is considered to be a sterile device.

Do not use BLEScath™ if the packaging is open or its contents are damaged[3].

Please follow your recommended hospital NICU infection control procedural guidelines.

What resources do you have for training and learning about BLEScath™?

- BLEScath™ Instructions for Use (IFU) MD0102A[3]
- BLEScath™ IFU Pocket Guide[3]
- BLEScath™ Animated Video[3] (Intratracheal Catheter for Less Invasive Administration of Pulmonary Surfactant) can be viewed at www.blescath.com or request a private link to our YouTube channel.
- Training Videos[3]
  - Guide to Less Invasive Administration of Pulmonary Surfactant.
  - Benefits of Less Invasive Surfactant Administration.
  - Reach out to us via our contact page for access to these resources.
- Literature Review www.blescath.com, www.bles.com
- BLEScath™ Brochure[3]
- BLES® Product-Monograph-2022[2]
- BLES® Brochure[2]
- LISA (Less Invasive Surfactant Administration) Brochure
- For on-site training and clinical support for healthcare professionals, please reach out to our Account Executives via the contact page.

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Who should I contact if I have a question about BLEScath™?

Please contact our Account Executive via the contact page or Tel: +1.519.457.2537

Where is BLEScath™ manufactured?

BLES Biochemicals Inc. proudly manufactures BLEScath™ in London, Ontario, Canada.

Where do you sell BLEScath™?

Currently, BLEScath™ is approved only for use in Canada. If you want to learn more about becoming a distributor outside of Canada, please connect with us via the contact page.

How is BLEScath™ packaged?

Each sterile package contains one 5 Fr catheter with an integrated SS stylet. 1 unit = 1 catheter / 10 units per case.

How do I place an order for BLEScath™?

Please reach out to us for detailed information via the contact page.

How much does BLEScath™ cost?

Please reach out to us for detailed information via the contact page.

What other products does BLES Biochemical Inc. manufacture?

BLES Biochemicals Inc. is an expert in pulmonary surfactant development and manufacturing. BLES® pulmonary surfactant is approved by Health Canada for use in neonates in Canada for rescue treatment for neonates suffering from Neonatal Respiratory Distress Syndrome (NRDS).
Explore more about BLES® visit us at www.blesbiochem.com

How long will it take to receive my order?

We will respond to the request for your order within one business day. Orders will be shipped via priority once confirmed.

Where do you ship to?

We will ship your new BLEScath™ product to the Canadian address noted on your purchase order.

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I have a question that is not listed here. How do I contact you?

There are several ways to contact us. The choice is yours!

Email us at info@blesbiochem.com, www.blescath.com, or via the contact page.

For immediate needs, contact us at Tel: +1.519.457.2537

Can you tell me about your customer service initiative?

BLES Biochemicals Inc. is committed to the highest level of customer support.

REFERENCES

1. BLEScath™ Brochure
2. BLES® Product Monograph, January 31, 2022.
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4. Herting E, Härtel C, Göpel W. Less invasive surfactant administration. Current Opinion in Pediatrics.2020;32(2):228–34.
5. Lemyre B, Lacaze-Masmonteil T, Shah PS, Bodani J, Doucette S, Dunn M, et al. Poractant alfa versus bovine lipid extract surfactant: Prospective Comparative Effectiveness Study. Journal of Perinatology. 2022;
6. Vento M, Bohlin K, Herting E, Roehr CC, Dargaville PA. Surfactant administration via thin catheter: A practical guide. Neonatology. 2019;116(3):211–26.

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