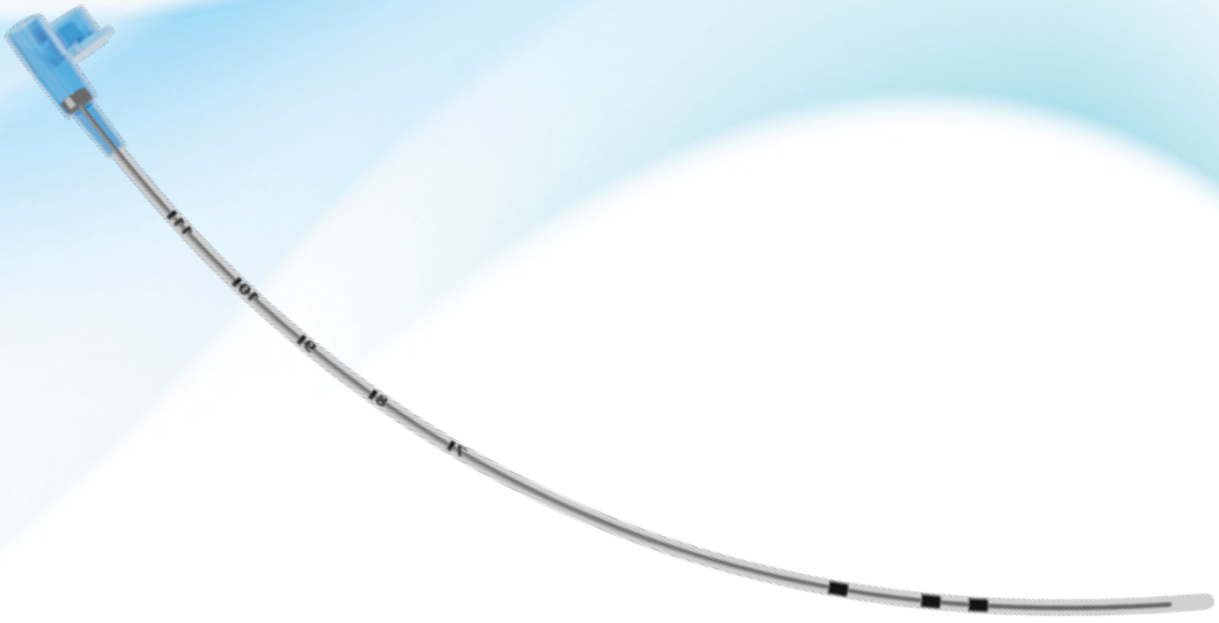
BLES Biochemicals Inc.



BLEScath™

Intratracheal catheter
For less invasive administration of pulmonary surfactant

An innovative solution for fast,
effective mitigation of NRDS

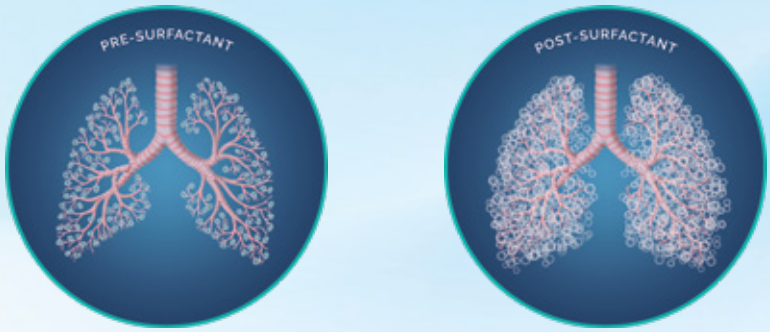
PROUDLY MADE IN CANADA

What is NRDS?

Neonatal respiratory distress syndrome (NRDS) is an important clinical syndrome responsible for a high rate of mortality and morbidity in premature (less than 37 weeks of gestational age) infants[8].

Surfactant is essential to normal lung function in babies[10]. NRDS is caused by a lack of, or dysfunction in, surfactant, the chemicals that line the lung air spaces and help keep the lung expanded[10]. Pulmonary surfactant is a lipoprotein complex responsible for preventing the collapse of alveoli and increasing lung compliance[5].

The low survival rate of preterm neonates affected by this condition propelled researchers to mitigate this issue. The development of exogenous pulmonary surfactants such as BLES® is innovative science impacting the treatment of NRDS.



What is LISA/MIST?

The less invasive surfactant administration (LISA) / 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 by continuous positive airway pressure (nCPAP).

LISA is intended for neonates ≥ 28 weeks gestation and/or ≥ 1000 grams. For non-spontaneous breathing patients please use the Intubate-Surfactant-Extubate (InSurE) technique.

- LISA reduces the necessity for intubation and mechanical ventilation[7,11].

- Meta-analyses have shown that LISA is superior to nCPAP alone or the InSurE technique in terms of avoidance of bronchopulmonary dysplasia (BPD) and intracranial hemorrhage (ICH)[6,7].

- Long-term follow-ups report better pulmonary function and neurocognitive outcomes[6].

What is BLEScath™?

BLEScath® is intended for the administration of BLES® using the LISA technique for rescue treatment of infants suffering from NRDS[3,4].

Pivotal Benefits

BLEScath™ supports the LISA method of surfactant administration. The administration of surfactant via a thin catheter compared with an ETT is associated with a reduced risk of death or BPD[1]. LISA may offer institutions cost savings by decreasing the need for ventilation, consumables, diagnostic procedures, and investigations[6].

BLEScath™ is a user-friendly device for healthcare practitioners who are not familiar with intubation or the use of Magill forceps[6]. BLEScath™ is designed explicitly for administration of BLES®. BLES® has a relatively low viscosity formulation and has been tested to pass through the holes in the stylet's anchor at the proximal end of BLEScath™. Other surfactants have not been tested with BLEScath™[4].

The integrated SS stylet is anchored and remains fixed in place.

User-friendly, intratracheal insertion catheter without the need for Magill forceps.

Markings: *7, 8, 9, 10, 11 cm* determine the "Tip to Lip" distance based on the weight of the patient in kilograms. The depth of insertion is 6 cm plus birthweight in kilograms[4].

The stylet allows the catheter to be bent into the user's preferred shape.

Stainless steel stylet is rigid yet flexible for ease of insertion.

Distal tip markings; 2, 2.5, 3.5 cm aid in determining the catheter insertion depth at the vocal cords.

Thin diameter 5Fr catheter maintains physiologic pharyngeal function.

Soft, rounded distal tip may reduce tissue trauma during insertion.

Technical Specifications

Size	5 Fr
Length	205 mm

Material Specifications

- Latex Free
- Stainless Steel (SS)
- DEHP Free
- Radiopaque polyvinyl chloride (PVC)

BLEScath's™ stainless steel stylet keeps its desired shape and does not migrate during the procedure[11]. The first of its kind. The integrated SS stylet is anchored and remains fixed in place.

BLES® has demonstrated success with LISA; research has shown successful administration of BLES® via LISA in 95.3% of patients[2].

Ordering Information

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

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References

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For more information please visit our website BLEScath.com

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