INSTRUCTIONS FOR USE

Instructions For Use The Inscope Direct Laryngoscope
Single-use Direct Laryngoscope

Manufactured under contract by:
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In this document, indicates conditions or practices that could lead to illness, injury, death, or damages to this or other equipment ("WARNING" and "CAUTION")

1. Fragile
2. For professional use only
3. Do not get wet
4. Temperature limits
5. Not made with Latex
6. Consult IFU
7. Non-sterile Units
8. In this document, indicates conditions or practices that could lead to illness, injury, death, or damages to this or other equipment ("WARNING" and "CAUTION")

Illustrations will be followed by instructions
The Inscope Direct Laryngoscope has two primary features: controllable suction and high-powered light. It is compatible with existing wall and battery powered portable suction and lighting. The Inscope Direct is single-use only and is equipped with an LED light source with a maximum expected duration at peak brightness of 10 minutes. The device blade is size 3.5 and is for use in medium to large adults.

Follow the steps below for proper use:

1. Prepare Suction:
   Connect standard 1/4-3/8 inch suction tubing to the Inscope Direct suction barb and to functioning portable or wall suction source.

2. Prepare LED Light:
   Remove the white button retaining tab and discard.

3. Activate LED Light:
   Approximately 1 minute before use, press the button once to activate LED. LED will remain turned on for 10 minutes. Light will remain at peak brightness for a minimum of 10 minutes. CAUTION: Do not shine light directly in eyes.

4. Engage Proximal Blade Suction:
   Release button to activate the proximal blade suction inlet. Leave button in neutral state for continuous proximal suction to clear re-accumulating fluids.

5. Engage Distal Tip Suction:
   Press and hold button to activate the distal tip suction inlet. Release button to activate the proximal blade suction inlet.

6. Insert Laryngoscope and Clear Airway:
   Insert the Inscope Direct laryngoscope into the right of midline and advance slowly toward trachea, using distal suction to clear the airway of secretions. CAUTION: Avoid engaging the distal suction when in direct contact with airway tissues and when blade tip is seated in vallecula.

7. Obtain View:
   Release the button before placing blade tip in the vallecula. Lift the laryngoscope handle up and to the left, being careful not to apply pressure to the patient’s teeth.

8. Manage Re-accumulating Fluids:
   If fluids re-accumulate with the blade seated in the vallecula, lower the blade straight down to quickly eliminate secretions. CAUTION: Do not engage distal tip suction with blade tip in vallecula.

9. Regain Line of Sight:
   With fluids managed, ensure blade tip remained in vallecula and lift handle up and to the left, being careful not to apply pressure to the patient’s teeth.

10. Insert Endotracheal Tube into Patient’s Trachea:
    Place the endotracheal tube into patient’s trachea.

INTENDED USE:
The Inscope Direct Laryngoscope is to be used to examine a patient’s upper airway and to aid in placement of a tracheal tube.

THE INSCOPE DIRECT FEATURES:
A rigid laryngoscope blade displaces the tongue, allowing a direct line of sight to the larynx and entrance to the trachea. The integrated suction clears fluid and other obstructions from the airway. Suction control is provided by an integrated valve. The Inscope Direct uses alkaline button batteries to power an integrated LED light source, which aids in viewing the larynx during intubation. The Inscope Direct is single-use. The Inscope Direct is for use in medium to large adults.

WARNING
Inspect each Inscope Direct laryngoscope prior to use for structural damage. Do not use if laryngoscope is damaged or if light/suction is not functioning. Do not attempt to remove or replace the integrated light source or batteries. Do not attempt to remove and/or replace the integrated light source or batteries. Inscope Direct laryngoscope may be subject to damage beyond control of manufacturer or supplier when in transit or storage.

The use of the Inscope Direct is restricted to skilled, authorized medics, nurses, paramedics, and doctors who are trained to use the device.

The Inscope Direct is single-use. The Inscope Direct is for use in medium to large adults.

RECOMMENDED STORAGE CONDITIONS:
- The Inscope Direct laryngoscope should be stored at room temperature. Conditions should not exceed -10° to 55° C.
- The package should be handled with care when placed in a storage room.

BATTERIES:
- The Inscope Direct light source contains alkaline batteries. Alkaline batteries do not contain toxic materials per federal EPA guidelines. Alkaline batteries are not regulated hazardous waste.

CAUTION
Do not attempt to remove and/or replace the integrated light source or batteries. Inscope Direct laryngoscope may be subject to damage beyond control of manufacturer or supplier when in transit or storage.

Inspect each Inscope Direct laryngoscope prior to use for structural damage. Do not use if laryngoscope is damaged or if light/suction is not functioning. Contact Inscope Medical Solutions, Inc. immediately if you encounter a damaged device or packaging.

The device must not be re-used. Reusing this disposable device might lead to infection, mechanical failure, or harm to the operator and/or patient.

The Inscope Direct is not MRI compatible.

The Inscope Direct is to be used on the order of and by a licensed physician or licensed practitioner.

Do not attempt to remove and/or replace the integrated light source or batteries.