



inscope

THE INSCOPE™ DIRECT

Single-Use Direct Laryngoscope

INSTRUCTIONS FOR USE

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



Manufactured under contract by:
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PN10516 Rev A



Fragile



For professional use only



Do not get wet



Temperature limits



Not made with Latex



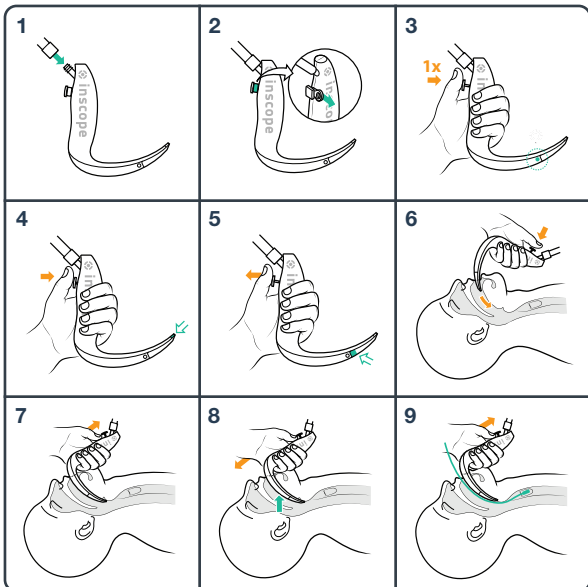
Consult IFU



Non-sterile Units



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 tubing. 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 cannot be turned off once activated. 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 scope to 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 re-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. Place the endotracheal tube into patient's trachea.
- 10 Dispose of Entire Device Assembly:**
Allow suction to remove fluids from the Inscope Direct before removing suction tubing from suction canister. Leave the Inscope Direct and suction tubing connected when discarding. Consider the Inscope Direct and suction tubing biohazard waste.

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. Contact Inscope Medical Solutions, Inc. immediately if you encounter a damaged device or packaging.

Treat used Inscope Direct laryngoscopes as medical biohazard infectious waste. Dispose of entire device assembly in suitable disposal unit or in accordance with your Environmental, Health, & Safety department and local regulations.

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

The device must not be reused. 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.

⚠ 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.

RECOMMENDED STORAGE CONDITIONS

- The Inscope Direct should be stored at room temperature. Conditions should not exceed -10° to 55° C.
- The packages 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.