

EXALT™ Model B Single-Use Bronchoscope

REFER TO THE DEVICE DIRECTIONS FOR USE FOR COMPLETE INSTRUCTIONS ON DEVICE USE. RX ONLY.
CAUTION: FEDERAL LAW (USA) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

Reuse Warning

For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

NOTE: The EXALT Model B Single-Use Bronchoscope has an anti-reuse function. Please see 'Time Remaining Indicator' section below for more information.

Intended Use/Indications For Use

The EXALT Model B Single-Use Bronchoscope is intended for use with the EXALT Monitor for endoscopic procedures within the airways and tracheobronchial tree.

Contraindications

Contraindications associated with the use of this device include:

- Patients for whom endoscopic procedures within the airways and tracheobronchial tree is medically contraindicated.

Warnings

- Do not use with High Frequency accessory devices.
- EXALT Model B images must not be used as an independent diagnostic of any pathology. Physicians must interpret and substantiate any finding by other means and in the light of the patient's clinical characteristics.
- Do not use Bronchoscope in the presence of flammable fluids or gases such as alcohol or oxygen. Doing so may result in fire and burns to the operator and patient.
- Do not use the Bronchoscope with any medical electrical equipment that does not comply with IEC 60601-1, and any applicable collateral and particular standards (e.g. IEC 60601-1-2, IEC 60601-2-18).
- Only use the Bronchoscope in conjunction with the EXALT Monitor. Connection to any other system may cause Bronchoscope or property damage or operator injury.

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Precautions

- Do not bump, drop, bend, torque, or pull any portion of the Bronchoscope. Doing so may cause damage to the Bronchoscope and thus, failure to operate appropriately.
- Use the Bronchoscope with caution in patients who have surgically altered anatomy. These conditions may prevent passage of the Bronchoscope.
- The EXALT Model B Bronchoscope was not designed to be compatible with a luer lock syringe.
- There is no guarantee that instruments selected solely using maximum insertion portion width and working length will be compatible in combination.
- There is no guarantee that instruments selected solely using the minimum instrument channel width will be compatible in combination.
- The slim version of EXALT Model B is not intended for use with accessory devices.

Adverse Events

Possible complications include, but may not be limited to:

- Perforation
- Bleeding
- Infection
- Tissue damage
- Burn
- Electric shock
- Bronchospasm
- Pneumothorax
- Airway Obstruction

Device Compatibility

The Bronchoscope is compatible with the EXALT Monitor. Additionally, the Bronchoscope is compatible with accessory devices that are compatible with the specifications listed below:

UPN	Minimum Working Channel	Minimum Working Length
M00524731	2.0mm	66cm
M00542751	2.6mm	66cm

Time Remaining Indicator

The EXALT Model B Bronchoscope is a single-use device. To help mitigate the potential for re-sterilization and re-use of the Bronchoscope, the EXALT Monitor provides a warning ⚠️ when there are 30 minutes remaining of the 12-hour use time limit. When the limit is reached, the Bronchoscope will no longer function and the Monitor will display an "SUD Reuse Error" screen.