



GALAXY

User Manual Addendum

Noah Medical Corporation Manufacturing

2075 Zanker Rd.
San Jose, CA 95131
Tel: +1-888-325-NOAH (6624)

Manufacturer Responsible for Placing Products on the Market

Noah Medical Corp.
2075 Zanker Rd.
San Jose, CA 95131
Tel: +1-888-325-NOAH (6624)
noahmed.com

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Galaxy System User Manual

Addendum on Compatible Third-party Biopsy Tools

This addendum to the Galaxy System User Manual provides updated information for Compatible Working Channel Tools/Instruments during a Galaxy Procedure. This IFU addendum applies to the Galaxy System™ Bronchoscope (GALB-001), Lot Numbers that start with 20, and finish with 042301 and higher (e.g., 2025042301, 2025042302, etc.), as well as those that start with 60, and finish with 061012 and higher (e.g., 6025061012, 6025061013, etc.).

Keep this addendum with your Galaxy System User Manual.

Compatible Equipment

Compatible Equipment

Below is information regarding tools/instruments tested and compatible with the Galaxy System™. The use of third-party tools is at the discretion of the hospital and the physician. Please consult Noah Medical prior to using any devices not listed below.

Working Channel Tools/Instruments

The Galaxy System™ is compatible with flexible working channel instruments with lengths greater or equal to 1100 mm (110 cm) that are designed to fit within a working channel with a 2.1 mm inner diameter.

Third-party tools that have been tested for compatibility with the working channel of the Galaxy System™ Bronchoscope include the following instruments:

Third-Party Tool	Model ID
Needles	
Olympus Periview Flex needle	NA-403D-2021
Arcpoint 21G needle	ILS-2100-PN
Forceps	
Boston Scientific Radial Jaw 4 forceps	M00513450
Brushes	
Boston Scientific Celebrity Single-Use Cytology Brush	M00516150
Others	
Olympus Endoscopic Radial Probe	UM-S20-17S
Medtronic (MDT) SuperDimension Marker Delivery Kit	SDMDK1000
ERBE Flexible Cryoprobe, Single-Use	Ø1.1mm, 20402-401



CAUTION: If the bending section of the bronchoscope is articulated sharply and advancement of a biopsy tool encounters increased insertion resistance, straighten the bending section as much as possible to enable resumed advancement of the tool. Use of excessive force during instrument insertion may damage the instrument and/or the bronchoscope or result in tissue injury including pneumothorax or bleeding. Third-Party Tools not listed above may

exhibit increased insertion resistance or may not advance when bronchoscope bending section is significantly articulated.

Customer Support

Only qualified service personnel should service or maintain hardware components. If you feel that the Galaxy System hardware components or associated features or functions do not perform as expected, or they provide results that are inconsistent with your established clinical and research protocols, contact Noah Medical Customer Service at +1-888-325-NOAH (6624).