



Products for Pulmonary Endoscopy



Pulmonary Endoscopy

To deliver high-quality patient care, you need a partner that provides innovative technologies, robust clinical and economic evidence, education, reimbursement support, and a portfolio of services. We are committed to working with you to pursue meaningful innovation, develop technologies, and provide support that offers greater value and makes a difference in the lives of your patients.



When we challenge conventional thinking,

We advance the standard of care.

EBUS DEVICES

Expect[™] **Pulmonary** Endobronchial Ultrasound Transbronchial Aspiration Needle <u>Acquire</u>[™] Pulmonary Fine Need Biopsy (FNB) Device **CoreDX**[™] Pulmonary Mini-Forceps

PULMONARY DEVICES

Radial Jaw[™] 4 Single-Use Biopsy Forceps

Cellebrity Single-Use Cytology Brushes

eXcelon[™] Single-Use Transbronchial Aspiration Needle

Zero Tip™ Single-Use Airway Retrieval Basket

Rescue™ Pulmonary Grasping Forceps

Pulmonary Compliance BronchKit Single-Use Bronchoscope Reprocessing Kit

STENTS & DILATION

CRE[™] Pulmonary Balloon Dilator

<u>Ultraflex</u>[™] Tracheobronchial Stent System

Expect[™] **Pulmonary**

Endobronchial Ultrasound Transbronchial Aspiration Needle

The Expect Pulmonary Ultrasound Transbronchial Aspiration Needle is designed to be used with endobronchial ultrasound endoscopes for ultrasound-guided fine needle aspiration of the submucosal and extramural lesions of the tracheobronchial tree and the gastrointestinal tract.

Reliability

Sharp needle tip grind is designed for precise penetration into the target area. Testing shows no deterioration in sample quality throughout a procedure.¹

Durability

- Cobalt chromium needle provides benefits over some stainless steel alloys including greater needle hardness and excellent tensile properties to deliver²:
 - Superior needle penetration²
 - Improved pushability and kink resistance²
 - Increased resistance to needle damage or deformation after multiple passes²
 - Thin wall of needle maximizing inner diameter for improved sample collection

Highly Visible Echogenic Pattern

- Extends onto needle tip to help provide precise guidance within the target site
- Helps to maintain needle tip visibility at all times during a procedure







¹Data on file.

²Catheter and Specialty Needle Alloys, an abstract from Materials & Processes for Medical Devices Conference & Exposition, Minneapolis, MN, August 10-12, 2009. Ultrasound and pathology images courtesy of Dr. Septimiu Murgu

Expect[™] Pulmonary

Endobronchial Ultrasound Transbronchial Aspiration Needle

Olympus Sco	ope Compatible				
Order Number	GTIN	Needle Size	Minimum Working Channel (mm)	Sheath Outer Diameter (mm)	Units
M005 5822 0	08714729861409	Expect Pulmonary 22Ga – Olympus Scope Compatible	2.0	1.6	Each
M005 5825 0	08714729861416	Expect Pulmonary 25Ga – Olympus Scope Compatible	2.0	1.4	Each
M005 5873 1	08714729893189	Expect Pulmonary Needle Adaptor – Olympus Scope Compati	tible N/A	N/A	Box 10
M005 5822 1	08714729861430	Expect Pulmonary 22Ga – Olympus Scope Compatible	2.0	1.6	Box 5
M005 5825 1	08714729861447	Expect Pulmonary 25Ga – Olympus Scope Compatible	2.0	1.4	Box 5

Acquire[™]**FNB**

Pulmonary Fine Needle Biopsy (FNB) Device

The Acquire Pulmonary EBUS-FNB Device is designed to be used with EBUS scopes for fine needle biopsy of submucosal and extramural lesions of the tracheobronchial tree and the gastrointestinal tract.



FNB of lung lesions may be performed during EBUS procedures when the tip design of a traditional Fine Needle Aspiration (FNA) needle is not optimal. Examples include, but are not limited to, lung cancer staging and diagnosis, and suspected lymphoma or sarcoidosis.

Franseen tip is designed to capture bigger tissue specimens

- > Three points provide stability at puncture
- Three symmetrical cutting surfaces with fully formed heels maximize tissue capture and minimize fragmentation

Histopathological Core Samples

> For 20x more tissue than same gauge FNA needle¹

Based on use of the Acquire needle in gastrointestinal procedures.



1. Termnykh, Lindsey M. et al. An exclusive fine needle biopsy approach to sampling solid lesions under EUS guidance: a case controlled study. Gastrointestinal Endoscopy. 2018: 87(6); AB427 - AB428.

Acquire

Pulmonary Fine Needle Biopsy (FNB) Device

Acquire Pulmonary Endobronchial Ultrasound Fine Needle Biopsy Device							
Order Number	GTIN	Product Description	Minimum Working Channel (mm)	Sheath O.D. (mm)	Units		
M005 5235 0	08714729986225	Acquire Pulmonary 22Ga – Olympus Scope Compatible	2.0	1.4	Each		
M005 5240 0	08714729986249	Acquire Pulmonary 25Ga – Olympus Scope Compatible	2.0	1.4	Each		
M005 5873 1	0871472983189	Expect Pulmonary Needle Adaptor – Olympus Scope Cor	npatible		Box 10		
M005 5235 1	08714729986232	Acquire Pulmonary 22Ga – Olympus Scope Compatible	2.0	1.4	Box 5		
M005 5240 1	08714729986256	Acquire Pulmonary 25Ga – Olympus Scope Compatible	2.0	1.4	Box 5		

CoreDX[™] **Pulmonary Mini-Forceps**

CoreDx is designed for intranodal histologic sample collection-a complementary tool for EBUS procedures.

Histopathological Core Samples

> For molecular analysis and diagnosis of sarcoidosis and lymphoma

Flexibility & Column Strength

- CoreDx is designed with flexibility to allow access to all regions within the transbronchial tree
- High Column Strength* allows for ease of entry through access hole when used in conjunction with EBUS-TBNA * BSC Data on file

Scope Compatibility

- CoreDx is compatible with all currently available EBUS scopes (Olympus, Pentax, and Fuji)
- Compatible with super slim bronchoscope (1.2mm working channel)



deliberate strokes advance the forceps to





Open jaws carefully under ultrasound visualization. Move forceps forward against the tissue to be sampled and close jaws. Slowly withdraw forceps keeping jaws closed.



Following a standard EBUS procedure, CoreDx is used as an adjunctive technique to obtain histologic samples.



ULTRASOUND REFERENCE POINTS

points to help maintain the scope position during instrument exchange.

With CoreDx at the end of the working channel, align the ultrasound image to your reference points. Then using short the location of planned biopsy.

CoreDX

Pulmonary Mini-Forceps

CoreDx Pulmonary Mini-Forceps						
Order Number	GTIN	Product Description	Minimum Working Channel (mm)	Sheath Length (mm)	Units	
M00 5152 20	08714729971054	Pulmonary mini-forceps	1.2	130	Each	



Radial Jaw^w 4

Single-Use Pulmonary Biopsy Forceps

The Radial Jaw 4 Pulmonary Biopsy Forceps are intended to collect tissue endoscopically for histologic examination.

Surgical Stainless Steel Jaw with Improved **Micromesh Teeth**

Designed to Provide:

- ➤ Tissue specimens for excellent sample handling and preparation
- Clean, precise bite for accurate histological diagnosis

Streamlined Catheter

Designed to Provide:

- Enhanced passability through tortuous anatomy
- ➤ The right balance of columnar strength and flexibility for excellent pushability and control during scope passage

Single-Use

 Eliminates the risk of transmitting patient-topatient disease



Radial Jaw 4 Pulmonary

Single-Use Biopsy Forceps

naulai J	aw 4 Siliyi	e-ose Fullionally Bio	psy roiceps	
Order		Product		
Number	GTIN	Description	Differentiator	

Order		Product		Jaw	Working	Minimum Working	
Number	GTIN	Description	Differentiator	OD (mm)	Length (cm)	Channel (mm)	Units
M005 1518 1	08714729792864	Single Use Biopsy Forceps	Pulmonary Standard Capacity	1.8	100	2.0	Box 5
M00515182	08714729799337	Single Use Biopsy Forceps	Pulmonary Standard Capacity	1.8	100	2.0	Box 20
M005 1519 1	08714729792871	Single Use Biopsy Forceps	Pulmonary Standard Capacity w/ Needle	e 1.8	100	2.0	Box 5
M005 1519 2	08714729818083	Single Use Biopsy Forceps	Pulmonary Standard Capacity w/ Needle	e 1.8	100	2.0	Box 20
M005 1520 1	08714729793281	Single Use Biopsy Forceps	Pulmonary Large Capacity	2.2	100	2.8	Box 5
M005 1520 2	08714729818076	Single Use Biopsy Forceps	Pulmonary Large Capacity	2.2	100	2.8	Box 20

Cellebrity[™] Single-Use Cytology Brush

The Cellebrity Cytology Brush is indicated for acquiring tissue samples used for the diagnosis of suspected pathology in the airway tree.

PTFE Sheath

 Designed to help reduce friction, facilitating passage through the scope

Stainless Steel Wire Shaft

Intended to provide strength to help resist kinking or bending during advancement

Bullet-Shaped Tip

Designed to help reduce tissue trauma

Ergonomic Handle

- Ergonomic handle with automatic stop
- > Facilitates single-hand brush advancement and withdrawal
- Helps reduce the risk of overwithdrawal and subsequent kinking of proximal shaft

Ergonomic Handle Cytology Brush

all a

Cytology Brush

Cellebrity

Single-Use Cytology Brushes

Cellebrity S	ingle-Use Cytolo	gy Brushes				
Order		Product	Required Working	Bristle	Sheath Length	
Number	GTIN	Description	Channel (mm)	0.D. (mm)	(cm)	Units
M005 1600 1	08714729138983	Cytology Brushes	2.0	1.0	140	Box 10
M005 1601 1	08714729138990	Cytology Brushes	2.0	1.5	140	Box 10
M005 1607 1	08714729139089	Cytology Brushes	2.0	1.9	100	Box 10
M005 1615 1	08714729014003	Cytology Brushes	2.0	1.9	150	Box 10

eXcelon™

Single-Use Transbronchial Aspiration Needle

The eXcelon Transbronchial Aspiration Needle is indicated for use in aspiration in carinal, paratracheal, and hilar lesions of the bronchial tree where biopsy forceps cannot obtain a submucosal sample.

Procedural Safety Features

- Button lock system is designed to reduce risk of accidental needle deployment during catheter advancement, potentially avoiding costly scope damage
- Fused distal coil and needle configuration is designed to help prevent needle detachment
- Clear catheter designed for visualization if blood is drawn during aspiration

High Performance Design

- "X-Catheter" is engineered to promote responsiveness and kink resistance for smooth needle penetration
- Distal coil is designed to promote tip flexibility while maintaining rigidity at the proximal end
- Needle internal volume is designed to provide increased space for specimen collection





eXcelon

Single-Use Transbronchial Aspiration Needle

eXcelon Sin	gle-Use Transbro	nchial Aspiration Needle	*Needle packag	ed with 20cc Syringe			
Order		Product	Needle	Needle Length	Catheter Length	Sheath O.D.	
Number	GTIN	Description*	Gauge	(mm)	(cm)	(mm)	Units
M005 6410 1	08714729456452	Transbronchial Aspiration Needle	19	15	130	1.8	Box 5
M005 6411 1	08714729456469	Transbronchial Aspiration Needle	20	15	130	1.8	Box 5
M005 6412 1	08714729456476	Transbronchial Aspiration Needle	21	15	130	1.8	Box 5

Zero Tip[™]Basket

Single-Use Airway Retrieval Basket

The Zero Tip Airway Retrieval Basket is indicated to be used to endoscopically remove foreign bodies in the airway.

Access

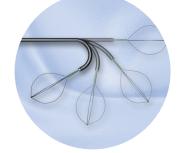
Designed for access to the upper lobes where rigid bronchoscopy may be insufficient

Low-Profile Tip Design

- Flattened distal surface of the basket designed to reduce tissue-to-tip interface for smooth manipulation
- Knotted basket tip designed to help prevent wire movement for more reliable foreign body capture
- Low-profile basket wire configuration facilitates proximity to foreign body, enhancing retrieval

Advanced Construction

- Nitinol wire construction designed to offer a kink-resistant, flexible wire for scope deflection
- Low-friction sheath designed for smooth scope passage
- Multi-layer sheath is designed to enhance pushability, while maintaining flexibility for enhanced scope deflection



Nitinol wire construction for enhanced scope deflection.



Zero Tip

Airway Retrieval Basket

Engineered for foreign body retrieval, even in the upper lobes.

Zero Tip Basket

Single-Use Airway Retrieval Basket

Zero Tip Single-Use Airway Retrieval Basket							
Order		Product	0.D.	Sheath Length	Working Opening	Basket Sheath	
Number	GTIN	Description	(mm)	(cm)	(mm)	Material	Units
M005 1320 0	08714729414995	Zero Tip Airway Retrieval Basket	0.8	120	12	Polyimide / PTFE	Each
M005 1321 0	08714729415008	Zero Tip Airway Retrieval Basket	1.0	120	16	Polyimide / PTFE	Each

Rescue[™] Pulmonary Grasping Forceps

The Rescue Pulmonary Grasping Forceps are intended to be used to retrieve foreign body and/or excised tissue endoscopically within the upper airways and tracheobronchial tree.

- Rat tooth shaped jaw designed for secure and strong grasp of intended object
- Insulated sheath designed to be atraumatic while maintaining passability and flexibility

Rescue[™] Pulmonary Grasping Forceps

Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with removal of foreign body

Rescue [™] Pulmonary Grasping Forceps							
Order Number	GTIN	Product Description	Maximum Insertion Portion Diameter (mm)	Working Length (cm)	Minimum Bronchoscope Channel Size (mm)	Jaw Opening Width (mm)	Units
M00515101	26948318968828	Rescue Pulmonary Grasping	Forceps 1.8	120	2.0	4.5	Box 5

Indications, Contraindications, Warnings and Instructions for Use can be found in the product labeling supplied with each device. CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

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Pulmonary Compliance BronchKit

Single-Use Bronchoscope Reprocessing Kit

The Boston Scientific Infection Prevention portfolio of products is designed to provide the components needed to comply with industry guidelines, mitigate cross-contamination risk, and reduce variability during bronchoscope reprocessing.

Pulmonary Compliance BronchKit Single-Use Bronchoscope Reprocessing Kit

Single-Use Bronchoscope Reprocessing Kit		
Name Item #	Compliance BronchKit Standard CBK-881-20	Compliance BronchKit Premium CBK-882-20
CinchPad [™] Endoscope transport pad	0	0
Gauze, 4X4, 4-ply, Non-Woven	0	0
SafeStart [™] bedside cleaning kit	0	0
Biohazard Label	0	0
HedgeHog [™] Double Bundle Cleaning Brush	0	0
20ml Syringe	0	0
EndoArmor [™] Plus Gown		0
Suction Tubing .25" x 10'		0

in communication

Single-Use Pulmonary Balloon Dilatation Catheter

The CRE Pulmonary Balloon Dilatation Catheter is intended to be used to endoscopically dilate strictures of the airway tree.

CRE Pulmonary Balloon Dilatation Catheter

Three-in-One Technology

- Designed for successive, gradual dilation of strictures
- Helps eliminate the need for multiple balloons to employ multi-size dilation therapy

First Balloon Indicated for the Airway

Indicated for airway stricture management

High Degree of Radial Vector Force

 Promotes low stricture compliance with little or no balloon waisting

0.035" Guidewire Compatible

➤ Designed for use with 0.035" guidewires, such as Jagwire[™] Pulmonary Guidewires

Rectilinear Shoulder Design

- Engineered to help promote endoscopic visualization
- Designed to provide greater usable balloon surface area during dilation

Radiopaque Markers

 Designed to facilitate fluoroscopic guidance of balloon positioning within a stricture

Inflation and Deflation

- ➤ Compatible with the Alliance[™] II Inflation System or CRE SteriFlate[™] Disposable Inflation Device
- Designed for rapid inflation and deflation when used with the Alliance II Inflation System or SteriFlate Disposable Inflation Device



Alliance[™] II Inflation System

CRE

Single-Use Pulmonary Balloon Dilator

CRE Pulmon	ary Balloon Dilators	5					
Order Number	GTIN	Diameter at 3 ATM	Diameter (mm) at Intermediate Pressure	Diameter (mm) at Maximum	Balloon Length (cm)	Catheter Length (cm)	Units
M005 5030 0	08714729456186	12	13.5 @ 4.5 atm	15 @ 8 atm	5.5	110	Each
M005 5031 0	08714729456193	15	16.5 @ 4.5 atm	18 @ 7 atm	5.5	110	Each
M005 5032 0	08714729456209	18	19 @ 4.5 atm	20 @ 6 atm	5.5	110	Each
M005 5033 0	08714729456216	8	9 @ 5.5 atm	10 @ 9 atm	3.0	110	Each
M005 5034 0	08714729456223	10	11 @ 5 atm	12 @ 8 atm	3.0	110	Each
M005 5035 0	08714729456230	12	13.5 @ 4.5 atm	15 @ 8 atm	3.0	110	Each

Inflation/Deflation Devices and Accessories

Alliance II Inflation System

Order		Product	
Number	GTIN	Description	Units
M005 5062 0	08714729283881	Inflation Handle	Each
M005 5060 1	08714729129332	Single-Use Syringe/	
		Gauge Assembly	Box 5

Order Number GTIN Description Units M00550630 00856877002506 CRE SteriFlate Disposable Inflation Device Each

Indications, Contraindications, Warnings and Instructions for Use can be found in the product labeling supplied with each device. (AUIION: Federal (USA) law restricts this device to sale by or on the order of a physician.

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Ultraflex™ Tracheobronchial Stent System

The Ultraflex Tracheobronchial Stent System is provided sterile in both covered and uncovered versions and is indicated for use in the treatment of tracheobronchial strictures produced by malignant neoplasms.

The Ultraflex Tracheobronchial Stent System is Designed to Address the Following Clinical Needs:

Accommodate Varying Airway Anatomy without Kinking

Knitted Nitinol Design

 Stent geometry is designed to adapt to anatomical contours and exert constant, radial pressure to maintain patency

Clear Secretions

Flexible Open Loop Design

- Epithelization of uncovered stent may promote mucociliary clearance
- **Resist Migration**

Uncovered Ends

 Epithelization of ends may limit migration



Resist Tumor Ingrowth

Silicone Covering

 Covering helps resist tumor growth

Ultraflex

Tracheobronchial Stent System

Ultraflex Tracheobronchial Partially Covered Stent System

			· · · ·	Commune of Chart			
		Expanded Stent O.D.	Expanded Stent	Compressed Stent Delivery System O.D.			
Order Number	GTIN	(mm)	Length (mm)	(mm)	Cover Length (mm)	Tip Max O.D. (mm)	Packaging
M005 7652 0	8714729842323	8	40	7	25	4.1	Each
M00576530	8714729842323	10	30	7	15	4.1	Each
	8714729842330	10	40	7	25	4.1	Each
M005 7654 0				1			
M005 7655 0	8714729842354	12	30	7	15	4.1	Each
M005 7656 0	8714729842361	12	40	7	25	4.1	Each
M005 7657 0	8714729842378	14	30	9	15	4.1	Each
M005 7658 0	8714729842385	14	40	9	25	4.1	Each
M005 7659 0	8714729842392	14	60	9	45	4.1	Each
M005 7660 0	8714729842408	14	80	9	65	4.1	Each
M005 7661 0	8714729842415	16	40	9	25	5.3	Each
M005 7662 0	8714729842422	16	60	9	45	5.3	Each
M005 7663 0	8714729842439	16	80	9	65	5.3	Each
M005 7664 0	8714729842446	18	40	11	25	5.3	Each
M005 7665 0	8714729842453	18	60	11	45	5.3	Each
M005 7666 0	8714729842460	18	80	11	65	5.3	Each
M005 7667 0	8714729842477	20	40	11	25	5.3	Each
M005 7668 0	8714729842484	20	60	11	45	5.3	Each
M005 7669 0	8714729842491	20	80	11	65	5.3	Each

Amplatz Super Stiff [™] Guidewire								
Order			OD	Length				
Number	GTIN	Description	(in)	(mm)	Tip Style	Packaging		
M005 5009 0	08714729301929 Amplatz Super Stiff Guidewire		.038	260	Straight	Each		
Jagwire [™] Single-Use Pulmonary Guidewire								
A 1								

Order			Length	
Number	GTIN	O.D. (in)	(cm)	Units
M005 1517 1	08714729455813	.035	180	Box 2

Delivery System

Low Profile

The compressed stent and delivery system have between a 5-9mm outer diameter. The system is designed to facilitate advancement across tumors and may be placed via flexible or rigid bronchoscopy

Flexibility

 The flexible delivery catheter is designed to enhance the ease of navigation through the airway

Radiopaque Markers

 Radiopaque markers on the delivery catheter are designed to target the deployed position of the stent

Distal or Proximal Release

 Different release systems are designed to allow the physician greater control over stent deployment Ultraflex Tracheobronchial Stent Delivery System

Mananan



Post Stent*

Ultraflex™

Tracheobronchial Stent System

Ultraflex Tracheobronchial Uncovered Stent System								
	Uncovered		Proximal	Expanded	Expanded	Uncovered	Tip Max	
Uncovered Distal	Distal Release	Uncovered	Release	Stent OD**	Stent Length	Compressed	OD	
Release	GTIN	Proximal Release	GTIN	(mm)	(mm)	Stent OD (mm)	(mm)	Units
-	-	M005 7641 0	08714729837770	8	20	7	4.1	Each
-	-	M005 7642 0	08714729837787	8	40	7	4.1	Each
-	-	M005 7643 0	08714729837794	10	20	7	4.1	Each
M005 7630 0	08714729837688	-	-	10	30	7	4.1	Each
-	-	M005 7644 0	08714729837800	10	40	7	4.1	Each
-	-	M005 7645 0	08714729837817	12	20	7	4.1	Each
M005 7631 0	08714729837695	-	-	12	30	7	4.1	Each
-	-	M005 7646 0	08714729837824	12	40	7	4.1	Each
-	-	M005 7647 0	08714729837831	14	20	9	4.1	Each
M005 7632 0	08714729837701	-	-	14	30	9	4.1	Each
-	-	M005 7648 0	08714729837848	14	40	9	4.1	Each
-	-	M005 7649 0	08714729837855	14	60	9	4.1	Each
M00576330	08714729837718	-	-	16	40	9	5.3	Each
M005 7634 0	08714729837725	-	-	16	60	9	5.3	Each
M005 7635 0	08714729837732	-	-	18	40	11	5.3	Each
M005 7636 0	08714729837749	-	-	18	60	11	5.3	Each
M005 7637 0	08714729837756	-	-	20	40	11	5.3	Each
M005 7638 0	08714729837763	-	-	20	60	11	5.3	Each

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death. *Image courtesy of Dr. David R. Riker **Data on file at Boston Scientific



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Ordering Information 1.888.272.1001

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