Contents

Minimum Required Working Channel

Adjustable Needle Length

Adjustable Working Length

REF

This document is applicable to the following products:

M00555500	M00555520
M00555501	M00555521
M00555510	M00555530
M00555511	M00555531

AU REP

Boston Scientific (Australia) Pty Ltd
PO Box 332
BOTANY NSW 1455 Australia
Free Phone 1800 676 133
Free Fax 1800 836 666

AR REP

Para obtener información de contacto de Boston Scientific Argentina SA, por favor, acceda al link bostonscientific.com/arg

EC REP

Boston Scientific Limited
Ballybrit Business Park
Galway IRELAND

Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752 USA
USA Customer Service +1-888-272-1001
www.bostonscientific.com

CE 2797

Boston Scientific

51533792-01

2023-03
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Expect™ Slimline (SL)

Endoscopic Ultrasound Aspiration Needle

Expect™ Slimline (SL)

FLEXIBLE

Endoscopic Ultrasound Aspiration Needle

℞ 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.

DEVICE DESCRIPTION

Contents

Package contents include:

- One (1) Expect Slimline (SL) Needle
- One (1) Vacuum Syringe
- One (1) One-Way Stopcock

Operating Principle

The Expect Slimline (SL) Endoscopic Ultrasound Aspiration Needle is an endoscopic ultrasound aspiration needle that can be coupled to the biopsy channel of a Curvilinear Array (CLA) Echoendoscope with a standard luer connection and delivered into the digestive tract. The device sheath length can be adjusted to accommodate different model echoendoscopes.

The needle is used to acquire aspiration samples from lesions and provide therapy within and adjacent to the digestive system's major lumens that can be identified and targeted using the echoendoscope. Both the sheath and needle length can be adjusted based on distance to the target lesion. The sheath and needle length adjustments are set and locked by the physician by using the locking knob mechanisms on the handle of the device.

An aspiration sample is obtained by penetrating the lesion with the needle while applying suction and manipulating the needle in a back and forth motion to aspirate cytology samples into the needle. The sample can be prepared per normal institutional protocol.

The Expect Slimline (SL) Needle has echogenic (visible under ultrasound) features at the distal end to facilitate real time visualization of the device under ultrasound.

NEEDLE SPECIFICATIONS

Working Length: 137.5 cm to 141.5 cm adjustable

Needle Length: 0 cm to 8 cm adjustable

Diameter: Three different needle sizes - 19 gauge, 22 gauge, and 25 gauge

M00555500	19 gauge OD: 1.10 mm	Minimum 2.8 mm Working Channel
M00555510	22 gauge OD: 0.72 mm	Minimum 2.4 mm Working Channel
M00555520	25 gauge OD: 0.52 mm	Minimum 2.4 mm Working Channel
M00555530	19 gauge flexible OD: 1.14 mm	Minimum 2.8 mm Working Channel

Materials

Contains cobalt: CAS No. 7440-48-4; EN No. 231-158-0. Defined as a 1B carcinogen and reproductive toxicant according to the European Commission in a concentration above 0.1% weight by weight.

Note: This device is made with stainless steel and cobalt alloys which contains cobalt. Current scientific evidence supports that stainless steels and cobalt alloys used in medical devices, do not cause an increased risk of cancer or adverse reproductive effects.

User Information

Read the entire instructions for use before using the Expect Slimline (SL) Needle as well as the instructions for use supplied by the manufacturers of injectable materials (fluids), fiducials, and accessory devices, if used. The Expect Slimline (SL) Needle should only be used by or under the supervision of physicians trained in Endoscopic Ultrasound procedures and Fine Needle Aspiration. A thorough understanding of the technical principles, clinical applications and risks associated with these procedures are necessary before using this device.

INTENDED USE / INDICATIONS FOR USE

The Expect Slimline (SL) Needle is designed to sample targeted submucosal and extramural gastrointestinal lesions through the accessory channel of a curvilinear echoendoscope. It can also be used for delivery of injectable materials (fluids) or fiducials into tissue or for passage of accessory devices.

Clinical Benefit Statement

To facilitate sampling of targeted submucosal and extramural gastrointestinal lesions through the accessory channel of a curvilinear echoendoscope. It can also be used for delivery of injectable materials (fluids) or fiducials into tissue or for passage of accessory devices.

CONTRAINDICATIONS

Contraindications for this device are those specific to the primary endoscopic procedure to be performed in gaining access to the desired site. Relative contraindications to submucosal and extramural aspiration include, but are not limited to: coagulopathy.

WARNINGS

The Expect Slimline (SL) Endoscopic Ultrasound Aspiration Needle should only be used to sample tissue where possible hemorrhage will not present a danger to patients. The device should be used with caution and only after careful consideration in patients with elevated bleeding times or coagulopathies- as patient injury, such as hemorrhage, can occur.

When targeting multiple sites, replace device for each site. Use of the device for multiple sites has not been established and may result in complications such as tumor seeding.

Do not use the same device to perform multiple indications. Use of the device for multiple indications has not been established and may result in complications such as tumor seeding.

Do not use this device in the heart or vascular system. Failure to observe this warning can result in patient injury.

PRECAUTIONS

The packaging and the device should be inspected prior to use. Do not use the device if the product or packaging is damaged.

ADVERSE EVENTS

Complications associated with the use of the Expect Slimline (SL) Needle may include:

- Allergic Reaction
- Aspiration
- Bleeding
- Cardiac Arrhythmia or Arrest
- Fiducial Migration
- Hypotension
- Infection
- Inflammation
- Pain
- Pancreatitis
- Perforation
- Peritonitis
- Respiratory Depression or Arrest
- Tumor Seeding

HOW SUPPLIED

The Expect Slimline (SL) Endoscopic Ultrasound Aspiration Needle is supplied STERILE using an ethylene oxide (EO) process. The packaging and device should be inspected prior to use. See product label for expiration date.

Device Details

Do not use if package is damaged or unintentionally opened before use.

Do not use if labeling is incomplete or illegible.

Handling and Storage

This product has no special handling or storage requirements.

OPERATIONAL INSTRUCTIONS

Device Selection

1. Choose appropriate size of device for the procedure.

Device Selection	19 Ga Flexible	19 Ga Standard	22 Ga	25 Ga
Sampling of submucosal and extramural gastrointestinal lesions (fine needle aspiration)	X	X	X	X
Delivery of injectable materials (fluids)	X	X	X	
Delivery of fiducials (luer loading)	X	X	X	
Delivery of fiducials (loading via needle tip)	X	X	X	
Passage of accessory devices*	X			

*19 Ga Flexible has demonstrated to be compatible for the delivery of the Mauna Kea Cellvizio AQ-Flex 19 Confocal Miniprobes accessory device.

See below table for needle size by fiducial dimensions:

Needle Size	Maximum Fiducial Outer Diameter (mm)	Maximum Fiducial Length (mm)
19 Ga Flexible and 19 Ga	0.80	10
22 Ga	0.46	10

Fiducials are not recommended for use with the 25 ga needle.

2. Inspect Boston Scientific device to ensure it is within acceptable shelf life constraints.

Preparation

1. Open device package and remove plastic insert containing FNA device and syringe.
2. Remove the device and syringe from the package.

Caution: Visually inspect the stopcock when removed from the package to confirm it is in the open position; otherwise, DO NOT USE IT. Call Boston Scientific Customer Service and return the product.

Caution: Visually inspect the device for loose, bent or broken parts, cracks, or other abnormalities. Inspect the catheter for any kinks or other damage. If an abnormality is detected, DO NOT USE. Broken parts, cracks, or kinks will hinder the mechanical operation of the Expect Slimline (SL) Needle. If the device fails to operate properly in any way or shows any signs of damage, DO NOT USE IT. Call Boston Scientific Customer Service and return the product.

Syringe Preparation

[For following indications: Sampling of submucosal and extramural gastrointestinal lesions (fine needle aspiration), delivery of injectable materials (fluids)].

BSC (MB IFU Template 16.5354 x 11.6929 A3, 923100610), IFU, MB, Expect Slimline, en, 51533792-01A

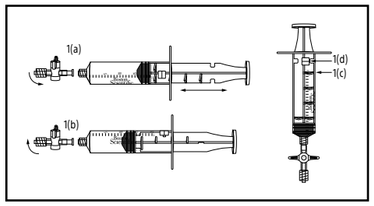

Figure 1.

1(a): Normal Sliding Use
1(b): Locks to Hold Vacuum
1(c): Locking Fins
1(d): Stop Pin

1. Examine the stopcock (Figure 1(a)). The stopcock has two luer connections to attach to the needle and syringe. Air can be exchanged with the stopcock in the open position. The stopcock is open when it is aligned parallel to the syringe; it is closed when perpendicular to the syringe (as shown).
2. Examine the syringe (Figure 1). The syringe barrel has one stop pin (Figure 1 (d)) and the syringe plunger has four locking fins (Figure 1(c)). The syringe plunger can be maneuvered within the syringe barrel to lock and unlock the syringe. To lock the syringe, pull back on the plunger until it aligns with the desired suction volume (Figure 1(a)). Turn the plunger clockwise so that the locking pin engages with the locking fins on the plunger (Figure 1(b)). Turn the plunger counterclockwise to release.

Note: The stopcock is required in order to maintain suction during the procedure.

Caution: If the stopcock is not set properly, adequate suction may not be achieved.

Procedure

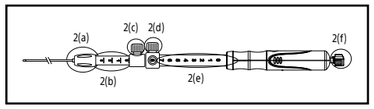

Figure 2.

2(a): Luer Attachment
2(b): Sheath Adjust Gauge
2(c): Sheath Adjust Lock
2(d): Needle Adjustment Lock
2(e): Needle Depth Gauge
2(f): Aspiration Port and Stylet Cap

OPERATIONAL INSTRUCTIONS

For additional instructions per indication, refer to specific instructions below.

Preparation Instructions:

1. Remove the needle from the package and examine it for damage.
2. Confirm that the needle is fully retracted and that the needle adjustment lock (Figure 2(d)) is secure in the zero position (Figure 2(e)).
3. Determine the appropriate sheath length relative to the length of the echoendoscope. Use the sheath adjustment lock (Figure 2(c)) to set the desired length of the sheath and lock it in place. Turn the sheath adjustment lock clockwise to lock the sheath in place. The distal end of the sheath should be visible on the endoscopic image.

Note: The reference numbers and markings on the sheath adjust gauge (Figure 2(b)) are intended as reference only.

4. Turn the endoscope elevator control knob to lower the elevator.

Caution: Failure to lower the elevator prior to insertion may cause damage to the device.

5. Introduce the catheter into the echoendoscope working channel. Slowly advance the device through the working channel on the echoendoscope.

Caution: If resistance is encountered, stop pushing and reposition the catheter or the echoendoscope. Pushing too hard could cause damage to the echoendoscope.

6. Continue to advance the device until it exits the echoendoscope and the sheath is visible in the endoscopic image. Tighten the luer attachment (Figure 2(a)) by turning clockwise to attach the device to the working channel port of the echoendoscope.

Note: If it is necessary to adjust the sheath length, loosen the sheath adjustment lock (Figure 2(c)) and reposition it to the appropriate reference point.

Caution: Do not tighten the luer connection too tightly to the echoendoscope as it may cause damage to the echoendoscope.

Caution: Prior to advancing the needle, ensure that the device is securely fastened to the echoendoscope and both the needle adjustment and sheath adjustment locks are secure. Failure to do so could result in damage to the echoendoscope.

Caution: Insufflation performance may be diminished when device is attached to the echoendoscope.

7. Verify the distance from the distal end of the sheath to the target site using the ultrasound image.
8. Adjust the needle penetration depth to the desired position using the needle adjustment lock (Figure 2(d)). To control the depth of needle penetration to the target site, loosen the needle adjustment lock by turning the knob counterclockwise. Align the needle adjustment lock with the appropriate reference number on the device handle. Lock in place by turning the needle adjustment lock clockwise.

Note: The reference numbers on the needle depth gauge (Figure 2(e)) are intended as reference only. The reference numbers represent needle extension (in centimeters) when the device is in a straight position.

9. Advance the needle by sliding the handle toward the echoendoscope in a slow and controlled motion to penetrate the target site while observing the ultrasound image.

Note: If it is necessary to adjust the amount of needle penetration, loosen the needle adjustment lock, reposition, and lock it to the appropriate reference point.

10. Remove the stylet (Figure 2(f)) from the aspiration port of the device by gently loosening and pulling it from the device handle.

Note: For delivery of fiducial via needle tip, stylet should be positioned per fiducial manufacturer's instructions. Continue to instructions below for delivery of fiducials (loading via needle tip).

Note: The stylet can be coiled and clipped together using the clip mechanism on the stylet cap (Figure 2(f)). The stylet should be retained for additional needle passes during the same procedure.

Caution: Failure to properly handle the stylet could result in damage to the device.

Warning: The stylet tip is sharp. Take precautions to ensure that the stylet is handled properly. After it has been removed from the needle, the stylet should be treated as infectious material and could create an infection risk.

After each procedure has been performed, follow instructions below for removal of needle.

Needle Removal:

1. Retract the needle fully into the sheath using the device handle by sliding the handle away from the echoendoscope until it stops moving. Secure the needle using the needle adjustment lock prior to withdrawing the device from the echoendoscope.

Warning: Ensure that the needle is fully retracted into the sheath. Failure to secure the needle could result in damage to the echoendoscope or injury to user.

2. Lower the elevator on the echoendoscope.

Caution: Failure to lower the elevator prior to withdrawal may cause damage to the device.

3. Detach the device from the echoendoscope by turning the luer connection counterclockwise. Slowly and carefully remove the device from the echoendoscope.

Warning: Do not use the same device to perform multiple indications. Use of the device for multiple indications has not been established and may result in patient complications such as tumor seeding.

Specific Instructions per Indication:

Sampling of submucosal and extramural gastrointestinal lesions (fine needle aspiration)

1. Prepare device, supplied syringe, and stopcock as previously noted. Rotate the stopcock to the closed position, perpendicular to the syringe. Pull the syringe plunger to the desired volume and use the locking fins and stop pin on the syringe to secure the plunger in place. (Figures 1(c) and 1(d)).

Caution: Methods of providing suction other than the supplied syringe are not recommended with this device.

2. Connect the supplied syringe to the aspiration port (Figure 2(f)) on the device handle.
3. Turn the stopcock to the open position (parallel to the device handle) to apply suction.
4. Maneuver the needle within the target site to maximize aspiration sample collection while observing needle penetration on the ultrasound image.
5. After an adequate number of passes have been made with the needle, close the stopcock by rotating until it is perpendicular to the syringe. This will stop suction.
6. Remove needle from echoendoscope (Refer to steps above).
7. After the device has been removed from the echoendoscope, release the needle adjustment lock and advance the device handle to extend the needle out of the sheath.
8. Remove the syringe and stopcock from the aspiration port.
9. Open the stopcock on the syringe by rotating it to the position that is parallel to the syringe. Pull the syringe plunger back to pull air into the syringe.
10. Reconnect the syringe to the aspiration port.
11. Push the syringe plunger forward to expel the aspiration sample from the needle.

Note: The locking fins and stop pin (Figures 1(c) and 1(d)) will have to be disengaged in order to pass air from the syringe.

Warning: Take precautions to ensure that the aspiration sample does not spray when it is expelled from the needle. The aspiration sample should be treated as infectious material and could create an infection risk.

12. Prepare the aspiration sample per institutional protocol.

Note: Multiple passes may be required to obtain an adequate aspiration sample.

13. If additional passes to the same target site are required, prepare the device by flushing the needle and wiping the stylet with sterile water or saline. Reinsert the stylet into the needle, examine the needle for damage, and repeat instructions.

Caution: Failure to flush the needle and wipe the stylet prior to reinserting the stylet into the needle could make the stylet difficult to pass or result in damage to the device.

Delivery of injectable materials (fluids)

1. Prepare device and load the supplied syringe with fluid.
2. Connect the supplied syringe to the aspiration port (Figure 2(f)) on the device handle.
3. Use the supplied syringe to inject desired quantity of fluid into the targeted injection site.
4. Remove needle from echoendoscope (Refer to steps above).
5. Determine if additional fluid needs to be injected. If so, prepare the device by flushing the needle with sterile water or saline, repeat instructions for delivery of injectable materials (fluids).

Delivery of fiducials (luer loading)

1. While preparing device per initial instructions and prior to turning the endoscope elevator control knob to lower the elevator, follow manufacturer's instructions to prepare the fiducial transfer device to load the fiducial.
2. Per the manufacturer's instructions, deliver the fiducial.

Caution: Ensure the stylet is not inadvertently advanced prior to or during needle insertion into the lesion. Advancing the stylet prior to or during needle insertion into the lesion may result in premature deployment of the fiducial.

Caution: Severe flexion of the endoscope may result in inability to deliver the fiducial.

3. Determine if additional fiducial needs to be placed. If so, repeat instructions for delivery of fiducials (luer loading).
4. Remove needle from echoendoscope (Refer to steps above).

Delivery of fiducials (loading via needle tip)

Note: Stylet should be positioned per fiducial manufacturer's instructions.

1. Prepare device and prior to turning the endoscope elevator control knob to lower the elevator, follow manufacturer's instructions to load and deliver the fiducial.

Caution: Ensure the stylet is not inadvertently advanced prior to or during needle insertion into the lesion. Advancing the stylet prior to or during needle insertion into the lesion may result in premature deployment of the fiducial.

Caution: Severe flexion of the endoscope may result in inability to deliver the fiducial.

2. Remove needle from echoendoscope (Refer to steps above).

Warning: The needle tip is sharp. Take precautions to ensure that the needle is handled properly. The needle should be treated as infectious material and could create an infection risk.

3. Determine if additional fiducial needs to be placed. If so, prepare the device by flushing the needle with sterile water or saline, repeat instructions for delivery of fiducials (loading via needle tip).

Caution: Failure to properly clean and flush the needle could lead to difficulty in completing the procedure as intended.

Passage of accessory devices

Note: The needle has demonstrated to be compatible for the delivery of the Mauna Kea Cellvizio AQ-Flex 19 Confocal Miniprobes accessory device.

1. Prepare device.
2. Follow manufacturer's instructions to select, prepare and preload the accessory device into the needle prior to turning the endoscope elevator control knob to lower the elevator.
3. Follow manufacturer's instructions for operating and removal of accessory device.
4. Remove needle from echoendoscope (Refer to steps above).

Disposal

To minimize the risk of infection or microbial hazards after use, dispose device and packaging as follows:

After use, device may contain biohazardous substances. The device and packaging should be treated and disposed of as biohazardous waste or have them treated and disposed of in accordance with any applicable hospital, administrative, and/or local government regulations. Use of a biohazardous container with biological hazard symbol is recommended. Untreated biohazardous waste should not be disposed of in the municipal waste system.

This device contains a sharps hazard. Take precautions to ensure that sharps are handled properly. Dispose of all sharps directly into a sharps disposal container labeled with a biological hazard symbol. Sharps waste should be safely disposed of using available sharps waste channels in accordance with hospital, administrative, and/or local government policy.

Post-Procedure

Any serious incident that occurs in relation to this device should be reported to the manufacturer, and to the relevant local regulatory authority.

PATIENT COUNSELING INFORMATION

Brief the patient on any relevant post-procedure instructions, contraindications, warnings, precautions and/or adverse events found within this Instructions for Use (IFU), pertaining to the patient.

WARRANTY

For device warranty information, visit (www.bostonscientific.com/warranty).

SYMBOL DEFINITIONS

Commonly used medical device symbols that appear on the labeling are defined at www.bostonscientific.com/SymbolsGlossary.

Additional symbols are defined at the end of this document.

BSC (MB IFU Template 16.5354 x 11.6929 A3,923100661), IFU, MB, Expect Slimline, en, 51533792-01A

MB Drawing 51308373

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