OLYMPUS® INSTRUCTIONS CE 0197

USA: CAUTION:
Federal law restricts this device to sale by or on the order of a physician.

DISPOSABLE CYTOLOGY BRUSH

BC-202D-1210/2010/3010/5010, BC-17W, BC-203D-2006

EndoTherapy™

1 Symbols

	Refer to instructions.	STERILE LOT	Sterilization lot number
	Single use only	STERILE EO	Sterilized using ethylene oxide
	Use by (expiration date)	LOT	Lot number
	Manufacturer	EC REP	Authorised representative in the European Community
	Keep away from sunlight		Importer (into European Union)
	Do not resterilize		Keep dry
	Not Made with Natural Rubber Latex		Do not use if package is damaged
			Temperature limitation

For US Customers only

For a Symbols Glossary, visit us: http://www.olympus-global.com/en/common/pdf/symbolsglossary.pdf

2 Intended Use

Do not use these instruments for any purpose other than their intended uses.

BC-202D-1210/2010/3010/5010, BC-203D-2006

These instruments have been designed to be used with Olympus endoscopes to collect tissue specimens in the tracheobronchial tree.

BC-17W

This instrument has been designed to be used with Olympus endoscopes to collect tissue specimens in the common bile duct.

3 Instruction Manual

This instruction manual contains essential information on using this instrument safely and effectively. Before use, thoroughly review this manual and the manuals of all equipment which will be used during the procedure and use the instruments as instructed.
If you have any questions or comments about any information in this manual, please contact Olympus.

4 User Qualifications

The operator of this instrument must be a physician or medical personnel under the supervision of a physician and must have received sufficient training in clinical endoscopic technique. This manual, therefore, does not explain or discuss clinical endoscopic procedures.

5 Signal Words

WARNING

Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.

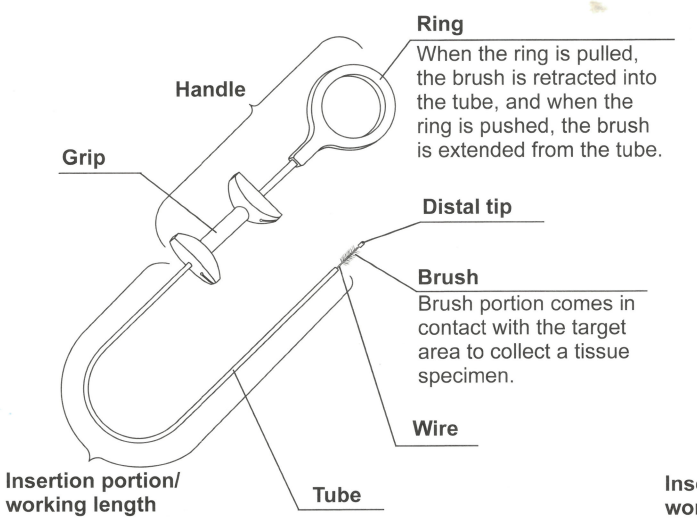
CAUTION

Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury. It may also be used to alert against unsafe practices or potential equipment damage.

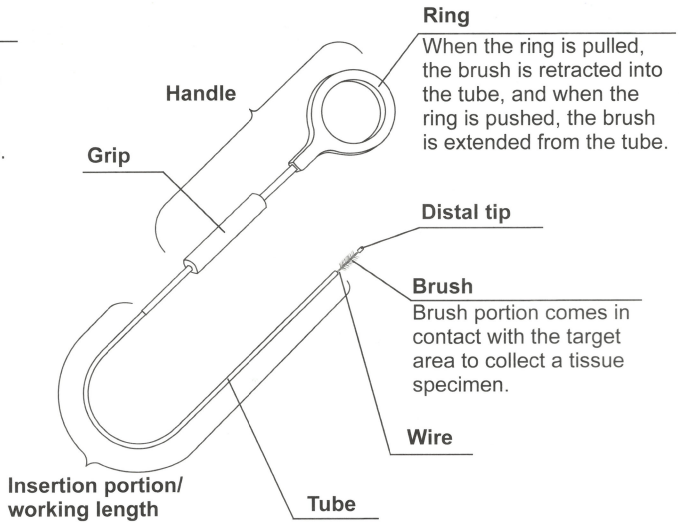
NOTE

Indicates additional helpful information.

6 Nomenclature and Functions

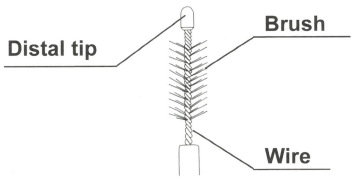


BC-202D-1210/2010/3010/5010



BC-17W/BC-203D-2006

Shape of the brush



NOTE

The distal tip of the BC-203D-2006 will extend from the tube even when the ring is fully extended.

7 Specifications

WARNING

Use this instrument only in combination with products recommended by Olympus.
If combined with products not recommended by Olympus, patient or operator injury, malfunction or equipment damage may result.

❍ Operating environment

Ambient temperature: 10 – 40°C (50 – 104°F), Relative humidity: 30 – 85%,
Air pressure: 700 – 1060 hPa (0.7 – 1.1 kgf/cm^2), (10.1 – 15.4 psia)

❍ Specification

Model		BC-202D -1210	BC-202D -2010	BC-202D -3010	BC-202D -5010	BC-203D -2006	BC-17W
Maximum insertion portion diameter (mm)		ø 1.8				ø 1.1	ø 1.6
Working length (mm)		1150					2500
Brush	Diameter (mm)	ø 1.2	ø 2	ø 3	ø 5	ø 2	ø 1
	Length (mm)	10				6	5
Compatible Olympus endoscopes (All of these parameters should be met)	Model and length	Working length 600 mm or less; BF					CHF-B20 only
	Channel inner diameter (mm) (color code)	ø 2, ø 2.2 (Blue); ø 2.6, ø 2.8 (Green); ø 3.2 (Yellow)				ø 1.2 (White or No color)	ø 1.7 (Violet)

Medical Devices Directive	CE 0197	This device complies with the requirements of Directive 93/42/EEC concerning medical devices. Classification: Class II a

8 Storage

WARNING

Do not store the sterile packages containing the instrument in places where they will become damaged, wet or improperly sealed. Otherwise, the sterility of the instrument may be compromised and pose an infection control risk or cause tissue irritation.

Store the instrument in the sterile package at room temperature in a clean and dry environment.
Do not store the instrument in direct sunlight. Ensure that the package is not crushed by surrounding objects during storage.

9 Preparation, Inspection and Operation

WARNING

- Do not use an instrument after the expiration date displayed on the sterile package. Doing so may pose an infection control risk or cause tissue irritation.
- Before use, prepare and inspect the instrument as instructed below. Should the slightest irregularity be suspected, do not use the instrument; use a spare instead. Damage or irregularity may compromise patient or user safety, such as infection control risk, tissue irritation, puncture hemorrhage or mucous membrane damage can result and can result in more severe equipment damage.

CAUTION

- Do not coil the insertion portion with a diameter of less than 15 cm. This could damage the insertion portion.
- Do not extend and retract the brush, or move it forward and/or back if resistance is encountered. Doing so may damage the endoscope and/or instrument.
- When using BC-203D-2006, do not use excessive force to retract the brush. This may also damage the instrument.

NOTE

The distal tip of the BC-203D-2006 will extend from the tube even when the ring is fully extended.

9.1 Preparation

❍ Spare instrument

Always have a spare instrument available in case of a malfunction.

9.2 Inspection

Wear appropriate personal protective equipment in accordance with their respective instruction manuals.

❍ Inspection of the sterile package

WARNING

Do not attempt to sterilize the instrument. This could pose an infection control risk, cause tissue irritation, equipment damage or malfunction.

Inspect the sterile package for tears, inadequate sealing or water damage. If the sterile package shows any irregularities, the sterile condition of the instrument may have been compromised. Do not use the instrument.

❍ Appearance inspection

1. While operating the ring to extend and retract the brush, confirm that the instrument is free from disconnection or looseness.
2. Gently run your fingertips over the entire length of the insertion portion to check for any crushed areas, excessive bends, broken areas or other damages.
3. Extend the brush from the tube. Make sure that there are no unraveled wires, disconnections, sharp protrusions, sharp edges or any other apparent abnormalities.
4. Make sure that there are no cracks on the handle.

❍ Inspection of operation

Straighten out the instrument. While holding the instrument's tube, operate the ring and confirm that the brush extends and retracts smoothly.

9.3 Operation

WARNING

- Appropriate personal protective equipment may include: Eye wear, face mask, moisture-resistant clothing and chemical-resistant gloves that fit properly and are long enough so that your skin is not exposed.
- When using the instrument, always wear appropriate personal protective equipment. Otherwise, blood, mucus and other potentially infectious material from the patient could pose an infection control risk.

- Do not insert the instrument into the endoscope unless you have a clear endoscopic field of view. If you cannot see the distal end of the insertion portion in the endoscopic field of view or in the X-ray images, do not use it. This could cause patient injury, such as punctures, hemorrhages or mucus membrane damage.
- Do not angulate the insertion portion of the endoscope abruptly while the distal end of the insertion portion is extended from the distal end of endoscope. This could cause patient injury, such as punctures, hemorrhages or mucus membrane damage.

❍ Insertion into the endoscope

WARNING

- Do not insert the instrument into the endoscope if the brush is not completely retracted into the tube and do not insert the instrument abruptly. The distal end of the insertion portion may extend from the distal end of the endoscope abruptly. This could cause patient injury, such as punctures, hemorrhages or mucus membrane damage. It may also damage the endoscope and/or instrument.
- Do not force the instrument if resistance to insertion is encountered. Reduce the angulation until the instrument passes smoothly.

CAUTION

- When inserting the instrument into the endoscope, retract the brush into the tube, hold it close to the biopsy valve and keep it as straight as possible relative to the biopsy valve. Otherwise, the instrument could be damaged.
- Take special care when insertion the BC-203D-2006, inserting into the endoscope, as it is much thinner and more fragile than the other models.

1. Pull the ring to retract the brush into the tube.
2. With the brush retracted into the tube, carefully insert the instrument into the biopsy valve.
3. Advance the instrument until the distal end of the insertion portion appears within the endoscopic field of view.
4. Slowly advance the distal end of the insertion portion toward the target area.

❍ Collect tissue

WARNING

Do not force the distal end of the insertion portion against body cavity tissue, and do not advance or extend the instrument abruptly. If you cannot see the distal end of the insertion portion properly, do not extend the brush from the tube or move the brush. Doing so could cause patient injury such as punctures, hemorrhages or mucus membrane damage.

NOTE

The distal tip of the BC-203D-2006 will extend from the tube even when the ring is fully extended.

1. Push the ring slowly to extend the brush from the tube and contact the target area.
2. Brush the target area to collect a tissue specimen.
3. Pull the ring to retract the brush into the tube.
4. Pull the distal end of insertion portion away from the target area.

❍ Withdrawing the instrument from the endoscope

WARNING

Do not withdraw the instrument from the endoscope quickly. This could scatter blood, mucous or other patient debris and pose an infection control risk.

CAUTION

Do not withdraw the instrument from the endoscope while the brush is extended from the tube or if resistance to withdrawal is encountered. Retract the brush into the tube and reduce the angulation until the instrument passes smoothly. This could damage the endoscope and/or instrument.

Withdraw the instrument from the endoscope.

10 Disposal

WARNING

- After use, dispose of the instrument in an appropriate manner. If it is not properly disposed of, it could pose an infection control risk.
- The instrument is a single-use, disposable item. Do not reuse or attempt to sterilize it. Reusing the instrument could pose an infection control risk and/or cause tissue irritation, and could not keep the function.

After using the instrument, dispose of it in an appropriate manner.

Manufactured by

OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho, Hachioji-shi, Tokyo 192-8507, Japan
Fax: (042)646-2429 Telephone: (042)642-2111

Distributed by

EC REP **OLYMPUS EUROPA SE & CO. KG**
(Premises/Goods delivery) Wendenstrasse 20, 20097 Hamburg, Germany
(Letters) Postfach 10 49 08, 20034 Hamburg, Germany
Fax: (040)23773-4656 Telephone: (040)23773-0

OLYMPUS AUSTRALIA PTY LTD
3 Acacia Place, Notting Hill, VIC 3168, Australia
Fax: (03)9543-1350 Telephone: (03)9265-5400

OLYMPUS AMERICA INC.
3500 Corporate Parkway, P.O. Box 610, Center Valley, PA 18034-0610, U.S.A.
Fax: (484)896-7128 Telephone: (484)896-5000

OLYMPUS LATIN AMERICA, INC.
5301 Blue Lagoon Drive, Suite 290 Miami, FL 33126-2097, U.S.A.
Fax: (305)261-4421 Telephone: (305)266-2332

KEYMED (MEDICAL & INDUSTRIAL EQUIPMENT) LTD.
KeyMed House, Stock Road, Southend-on-Sea, Essex SS2 5QH, United Kingdom
Fax: (01702)465677 Telephone: (01702)616333

OLYMPUS KOREA CO., LTD.
(Seocho-dong, Majestar City Tower One), 2F & 3F, 12, Seocho-daero 38-gil, Seocho-gu, Seoul, 06655, Republic of Korea
Fax: (02)6255-3210 Telephone: 1544-3200

OLYMPUS (BEIJING) SALES & SERVICE CO., LTD.
A8F, Ping An International Financial Center, No. 1-3, Xinyuan South Road, Chaoyang District, Beijing, 100027 P.R.C.
Fax: (86)10-5976-1299 Telephone: (86)10-5819-9000

OLYMPUS MOSCOW LIMITED LIABILITY COMPANY
Elektrozavodskaya str. 27 bld.8, 107023 Moscow, Russia
Fax: (7)495-926-7072 Telephone: (7)495-926-7077

OLYMPUS SINGAPORE PTE LTD
438B Alexandra Road #03-07/12, Alexandra Technopark Blk B, Singapore 119968
Fax: 6834-2438 Telephone: 6834-0010

©2001 OLYMPUS MEDICAL SYSTEMS CORP. All rights reserved.

Printed in Japan 20220322 M2000