OLYMPUS®

INSTRUCTIONS

ET

OLYMPUS ENDO-THERAPY

BIOPSY FORCEPS

FB-7U-1
FB-11K-1
FB-13E/K/Q/U-1
FB-15C/K-1
FB-19SX/C/K/N-1
FB-20C-1
FB-21SX/C/K-1
FB-22C-1
FB-23K-1
FB-24E/K/Q/U-1
FB-25F/K-1
FB-26N-1
FB-28R/U/Y-1
FB-34C/K-1
FB-35C-1
FB-36C/K-1
FB-37K/U-1
FB-38W-1
FB-44D-1
FB-50K/Q/U-1
FB-51K-1
FB-52C/K-1
FB-53K/Q/U-1
FB-54K/Q/U-1
FB-55K/Q/U-1

AUTOCLAVABLE

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

Contents

Symbols

The meaning(s) of the symbol(s) shown on the pack and/or this instrument are as follows:

⚠ Refer to instructions.

Important Information-Please Read Before Use

Intended Use

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

- **FB-7U-1, FB-11K-1, FB-13E/K/Q/U-1, FB-23K-1, FB-25F/K-1, FB-26N-1, FB-28R/U/Y-1, FB-38W-1, FB-50K/Q/U-1, FB-51K-1, FB-53K/Q/U-1, FB-54K/Q/U-1, FB-55K/Q/U-1**

These instruments have been designed to be used with an Olympus endoscope to collect tissue within the digestive tract.

- **FB-15C/K-1, FB-19SX/C/N-1, FB-21SX/C/K-1, FB-34C/K-1, FB-44D-1, FB-52C/K-1**

These instruments have been designed to be used with an Olympus endoscope to collect tissue within the digestive tract, respiratory organs, female reproductive organs and urinary organs.

- **FB-20C-1, FB-22C-1, FB-24E/K/Q/U-1, FB-35C-1, FB-36C/K-1, FB-37K/U-1,**

These instruments have been designed to be used with an Olympus endoscope to collect tissue within the digestive tract and respiratory organs.

Instruction Manual

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

User Qualifications

The operator of this instrument must be a physicia medical personnel under the supervision of a physi and must have received sufficient training in clir endoscopic technique. This manual, therefore, does explain or discuss clinical endoscopic procedures.

Instrument Compatibility

Refer to the Tables in Section 2.2, "Specifications confirm that this instrument is compatible with the anci equipment being used. Using incompatible equipment result in patient injury or equipment damage.

Reprocessing and Storage

This instrument was not sterilized before shipment. Before using this instrument for the first time, reprocess it according to the instructions in Chapter 4, "Reprocessing".

After using this instrument, reprocess and store it according to the instructions in Chapter 4, "Reprocessing" and Chapter 5, "Storage". Improper and/or Incomplete reprocessing or storage can present an infection control risk, cause equipment damage or reduce performance.

Repair and Modification

This instrument does not contains user-serviceable parts. Do not disassemble, modify or attempt to repair it; patient or user injury and/or equipment damage can result.

Signal Words

The following signal words are used throughout this manual:

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.

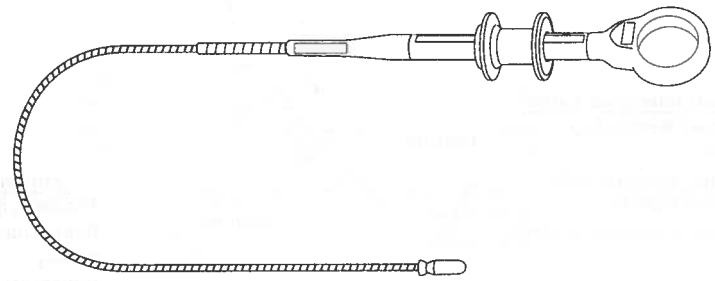
NOTE Indicates additional helpful information.

Chapter 1 Checking the Packag Contents

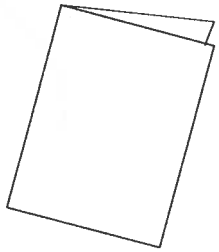
1.1 Checking the Package Contents

Match all items in the package with the components sh below. Inspect each item for damage. If the instrume damaged, a component is missing or you have questions, do not use the instrument; immediately cor Olympus.

This instrument was not sterilized before shipm Before using this instrument for the first time, reproce according to the instructions in Chapter 4, "Reprocessi



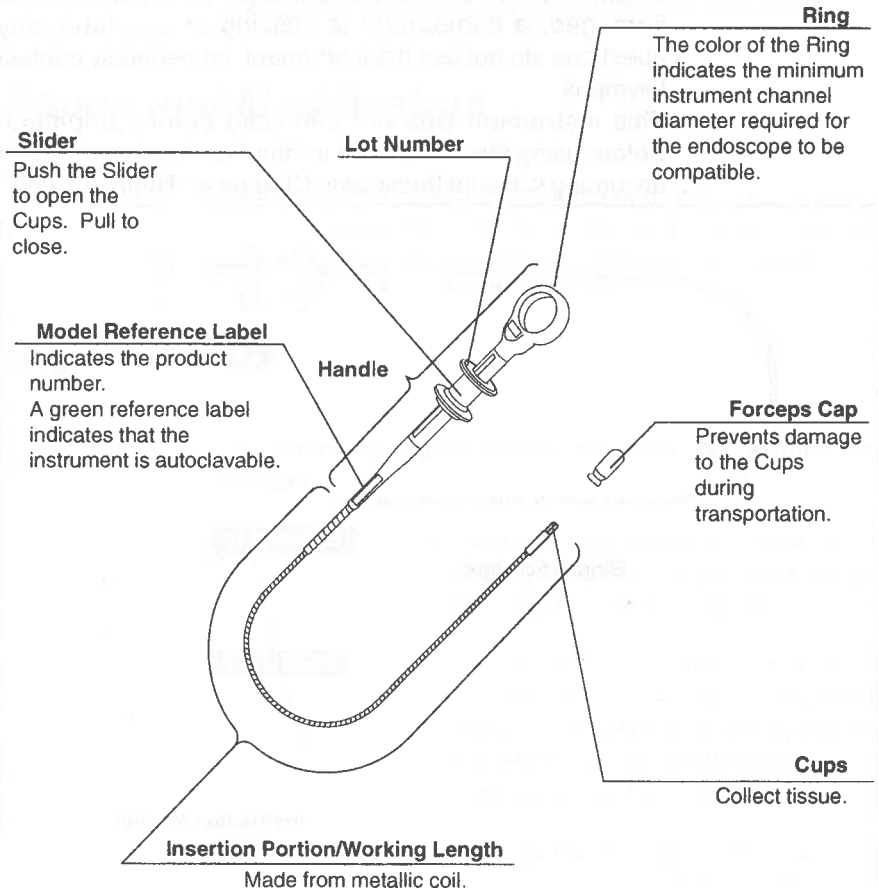
Biopsy Forceps

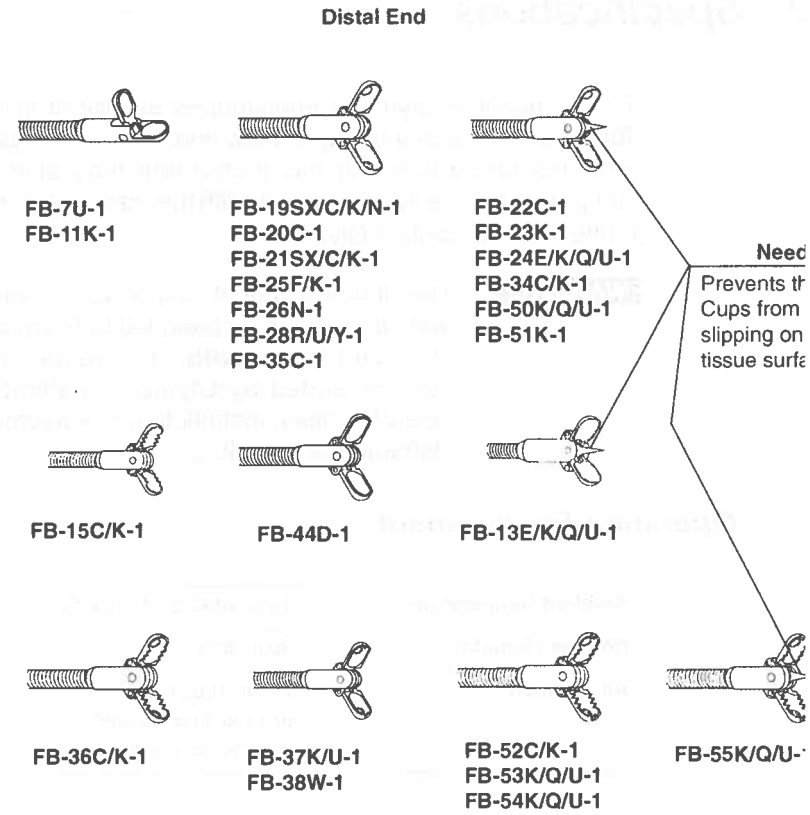


Instruction Manual

Chapter 2 Instrument Nomenclature and Specifications

2.1 Nomenclature and Functions





2.2 Specifications

The compatible Olympus endoscopes are listed in the Tables on the following pages. New endoscopes released after the introduction of this instrument may also be compatible for use in combination with this instrument. For further details, contact Olympus.

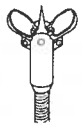
WARNING Use this instrument only in combination with products recommended by Olympus. If combined with products not recommended by Olympus, patient or operator injury, malfunction or equipment damage may result.

Operating Environment

Ambient Temperature	10 to 40°C (50 to 104°F)
Relative Humidity	30 to 85%
Air Pressure	700 to 1060 hPa (0.71 to 1.08 kgf/cm^2) (10.1 to 15.4 psia)

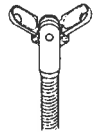
Specifications

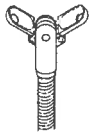
Model		**FB-7U-1**	**FB-11K-**
Shape of the Cups		**Alligator Type** 	
Maximum Insertion Portion Diameter (mm)		ø 2.4	
Working Length (mm)		2300	1550
With Needle		NO	
Fenestrated Cups		NO	
Compatible Olympus Endoscopes (All of these parameters should be met.)	**Model and Length**	Working length less than 1850 mm; EF, GIF, OGF, GF, GTF, JF, TJF, SIF (SIF-10 only), CF, PCF, OSF	Working length less than 1100 n EF, GIF, OC GF, GTF, C (Exclude I-, L-length), C
	Channel Inner Diameter (mm) (Color Code)	ø 2.8, ø 3.2 (Yellow) ø 3.7, ø 4.2, ø 6 (Orange) ø 5.5 (Pink)	ø 2.8, ø 3 (Yellow) ø 3.7, ø (Orange

Model		FB-13E-1	FB-13K-1
		Standard Type	
Shape of the Cups			
Maximum Insertion Portion Diameter (mm)		ø 3.4	
Working Length (mm)		1200	1550
With Needle		YES	
Fenestrated Cups		NO	
Compatible Olympus Endoscopes (All of these parameters should be met.)	Model and Length	Working length less than 750 mm;	Working length less than 1100 mm; GIF
	Channel Inner Diameter (mm) (Color Code)	ø 3.7 (Orange)	ø 3.7, ø 6 (Orange)

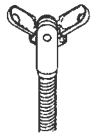
Model		FB-13Q-1	FB-13U-
		Standard Type	
Shape of the Cups			
Maximum Insertion Portion Diameter (mm)		ø 3.4	
Working Length (mm)		1950	2300
With Needle		YES	
Fenestrated Cups		NO	
Compatible Olympus Endoscopes (All of these parameters should be met.)	Model and Length	Working length less than 1500 mm; GIF, TJF, CF (I-length only)	Working length less than 1850 r GIF, TJF, C
	Channel Inner Diameter (mm) (Color Code)	ø 3.7, ø 4.2, ø 6 (Orange) ø 5.5 (Pink)	

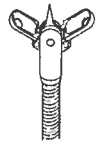
Model		FB-15C-1	FB-15K-1
Shape of the Cups		Alligator Jaws 	
Maximum Insertion Portion Diameter (mm)		ø 1.8	
Working Length (mm)		1050	1550
With Needle		NO	
Fenestrated Cups		NO	
Compatible Olympus Endoscopes (All of these parameters should be met.)	Model and Length	Working length less than 600 mm; CHF, BF, ENF, CYF, HYF, OSF	Working length less than 1100 mm; EF, GIF, OGF, GF, GTF, CHF, CF (Exclude I-, L-length), OSF, BF, ENF, CYF, HYF
	Channel Inner Diameter (mm) (Color Code)	ø 2, ø 2.2 (Blue) ø 2.6 (Green) ø 2.8, ø 3.2 (Yellow)	ø 2, ø 2.2 (Blue) ø 2.6 (Green) ø 2.8, ø 3.2 (Yellow) ø 3.7, ø 6 (Orange)

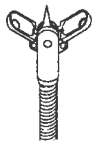
Model		FB-19SX-1	FB-19(
Shape of the Cups		Standard Type 	
Maximum Insertion Portion Diameter (mm)		ø 1.8	
Working Length (mm)		700	105(
With Needle		NO	
Fenestrated Cups		YES	
Compatible Olympus Endoscopes (All of these parameters should be met.)	Model and Length	Working length less than 400 mm; CHF, OSF (OSF-2-35 only), ENF, CYF, HYF	Working length les than 600 CHF, OS ENF, CYI HYF
	Channel Inner Diameter (mm) (Color Code)	ø 2, ø 2.2 (Blue) ø 2.6 (Green)	ø 2, ø (Blue ø 2.ı (Gree ø 2.8, ø (Yello

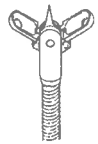
Model		FB-19K-1	FB-19N-1
Shape of the Cups		Standard Type 	
Maximum Insertion Portion Diameter (mm)		ø1.8	
Working Length (mm)		1550	1800
With Needle		NO	
Fenestrated Cups		YES	
Compatible Olympus Endoscopes (All of these parameters should be met.)	Model and Length	Working length less than 1100 mm; EF, GIF, OGF, GF, CHF, CF (Exclude I-, L-length), OSF, BF, ENF, CYF, HYF	Working length less than 1350 mm; EF, GIF, OGF, GF, GTF, JF, TJF, CHF, CF (Exclude L-length), OSF, BF, ENF, CYF, HYF
	Channel Inner Diameter (mm) (Color Code)	ø 2, ø 2.2 (Blue) ø 2.6 (Green) ø 2.8, ø 3.2 (Yellow) ø 3.7, ø 6 (Orange)	ø 2, ø 2.2 (Blue) ø 2.6 (Green) ø 2.8, ø 3.2 (Yellow) ø 3.7, ø 4.2, ø 6 (Orange) ø 5.5 (Pink)

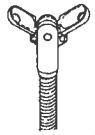
Model		FB-20C-1	FB-21S
Shape of the Cups		Standard Type 	
Maximum Insertion Portion Diameter (mm)		ø 2.2	ø 1.8
Working Length (mm)		1050	700
With Needle		NO	
Fenestrated Cups		YES	
Compatible Olympus Endoscopes (All of these parameters should be met.)	Model and Length	Working length less than 600 mm; CHF, OSF, BF	Working length les than 400 CHF, OSI (OSF-2-3 only), EN CYF, HYF
	Channel Inner Diameter (mm) (Color Code)	ø 2.6 (Green) ø 2.8, ø 3.2 (Yellow)	ø 2, ø 2 (Blue ø 2.6 (Gree

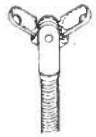
Model		FB-21C-1	FB-21K-1
Shape of the Cups		Standard Type 	
Maximum Insertion Portion Diameter (mm)		ø 1.8	
Working Length (mm)		1050	1550
With Needle		NO	
Fenestrated Cups		YES	
Compatible Olympus Endoscopes (All of these parameters should be met.)	Model and Length	Working length less than 600 mm; CHF, OSF, BF, ENF, CYF, HYF	Working length less than 1100 mm; EF, GIF, OGF, GF, GTF, CHF, CF (Exclude I-, L-length), OSF, BF, ENF, CYF, HYF
	Channel Inner Diameter (mm) (Color Code)	ø 2, ø 2.2 (Blue) ø 2.6 (Green) ø 2.8, ø 3.2 (Yellow)	ø 2, ø 2.2 (Blue) ø 2.6 (Green) ø 2.8, ø 3.2 (Yellow) ø 3.7, ø 6 (Orange)

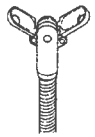
Model		FB-22C-1	FB-23K
Shape of the Cups		Standard Type 	
Maximum Insertion Portion Diameter (mm)		ø 2.2	ø 2.4
Working Length (mm)		1050	1550
With Needle		YES	
Fenestrated Cups		YES	
Compatible Olympus Endoscopes (All of these parameters should be met.)	Model and Length	Working length less than 600 mm; CHF, OSF, BF	Working length les than 1100 EF, GIF, C GF, GTF, CF (Exclu I-, L-lengtl OSF
	Channel Inner Diameter (mm) (Color Code)	ø 2.6 (Green) ø 2.8, ø 3.2 (Yellow)	ø 2.8, ø (Yellov ø 3.7, ø (Orang

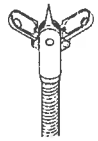
Model		FB-24E-1	FB-24K-1
Shape of the Cups		Standard Type 	
Maximum Insertion Portion Diameter (mm)		ø 2.4	
Working Length (mm)		1200	1550
With Needle		YES	
Fenestrated Cups		YES	
Compatible Olympus Endoscopes (All of these parameters should be met.)	Model and Length	Working length less than 750 mm; EF, CF (S-length only), OSF, BF	Working length less than 1100 mm; EF, GIF, OGF, GF, GTF, CF (Exclude I-, L-length), OSF, BF
	Channel Inner Diameter (mm) (Color Code)	ø 2.8, ø 3.2 (Yellow)	ø 2.8, ø 3.2 (Yellow) ø 3.7, ø 6 (Orange)

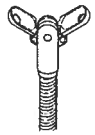
Model		FB-24Q-1	FB-24U
Shape of the Cups		Standard Type 	
Maximum Insertion Portion Diameter (mm)		ø 2.4	
Working Length (mm)		1950	2300
With Needle		YES	
Fenestrated Cups		YES	
Compatible Olympus Endoscopes (All of these parameters should be met.)	Model and Length	Working length less than 1500 mm; EF, GIF, OGF, GF, GTF, JF, TJF, CF (Exclude L-length), PCF (I-length only), OSF, BF	Working length les than 1850 EF, GIF, C GF, GTF, TJF, SIF (SIF-10 o CF, PCF, BF
	Channel Inner Diameter (mm) (Color Code)	ø 2.8, ø 3.2 (Yellow) ø 3.7, ø 4.2, ø 6 (Orange) ø 5.5 (Pink)	

Model		FB-25F-1	FB-25K-1
Shape of the Cups		Standard Type 	
Maximum Insertion Portion Diameter (mm)		ø 2.4	
Working Length (mm)		1250	1550
With Needle		NO	
Fenestrated Cups		YES	
Compatible Olympus Endoscopes (All of these parameters should be met.)	Model and Length	Working length less than 800 mm; EF, CF (S-length only), OSF	Working length less than 1100 mm; EF, GIF, OGF, GF, GTF, CF (Exclude I-, L-length), OSF
	Channel Inner Diameter (mm) (Color Code)	ø 2.8, ø 3.2 (Yellow)	ø 2.8, ø 3.2 (Yellow) ø 3.7, ø 6 (Orange)

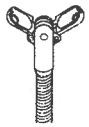
Model		FB-26N-1	FB-28R-
Shape of the Cups		Standard Type 	
Maximum Insertion Portion Diameter (mm)		ø 2.4	
Working Length (mm)		1800	2050
With Needle		NO	
Fenestrated Cups		YES	
Compatible Olympus Endoscopes (All of these parameters should be met.)	Model and Length	Working length less than 1350 mm; EF, GIF, OGF, GF, GTF, JF, TJF, CF (Exclude L-length), PCF (I-length only), OSF	Working length less than 1600 EF, GIF, O GF, GTF, TJF, CF (Exclude L-length), (I-length o OSF
	Channel Inner Diameter (mm) (Color Code)	ø 2.8, ø 3.2 (Yellow) ø 3.7, ø 4.2, ø 6 (Orange) ø 5.5 (Pink)	

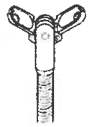
Model		FB-28U-1	FB-28Y-1
Shape of the Cups		Standard Type 	
Maximum Insertion Portion Diameter (mm)		ø 2.4	
Working Length (mm)		2300	2700
With Needle		NO	
Fenestrated Cups		YES	
Compatible Olympus Endoscopes (All of these parameters should be met.)	Model and Length	Working length less than 1850 mm; EF, GIF, OGF, GF, GTF, JF, TJF, CF, PCF, SIF (SIF-10 only), OSF	Working length less than 2250 mm; EF, GIF, OGF, GF, GTF, JF, TJF, CF, PCF, SIF, OSF
	Channel Inner Diameter (mm) (Color Code)	ø 2.8, ø 3.2 (Yellow) ø 3.7, ø 4.2, ø 6 (Orange) ø 5.5 (Pink)	

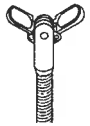
Model		FB-34C-1	FB-34K-
Shape of the Cups		Standard Type 	
Maximum Insertion Portion Diameter (mm)		ø 1.8	
Working Length (mm)		1050	1550
With Needle		YES	
Fenestrated Cups		YES	
Compatible Olympus Endoscopes (All of these parameters should be met.)	Model and Length	Working length less than 600 mm; CHF, OSF, BF, ENF, CYF, HYF	Working length less than 1100 EF, GIF, O GF, GTF, C CF (Exclu I-,L-length) OSF, BF, E CYF, HYF
	Channel Inner Diameter (mm) (Color Code)	ø 2, ø 2.2 (Blue) ø 2.6 (Green) ø 2.8, ø 3.2 (Yellow)	ø 2, ø 2. (Blue) ø 2.6 (Green ø 2.8, ø 3 (Yellow ø 3.7, ø (Orange
	Other	Exclude BF-1T20/30, BF-XT20/30	

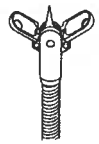
Model		FB-35C-1
		Standard Type
Shape of the Cups		
Maximum Insertion Portion Diameter (mm)		ø 2.4
Working Length (mm)		1050
With Needle		NO
Fenestrated Cups		YES
Compatible Olympus Endoscopes (All of these parameters should be met.)	Model and Length	Working length less than 600 mm; OSF, BF
	Channel Inner Diameter (mm) (Color Code)	ø 2.8, ø 3.2 (Yellow)

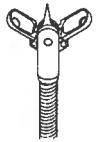
Model		FB-36C-1	FB-36K-
		Alligator Jaws	
Shape of the Cups			
Maximum Insertion Portion Diameter (mm)		ø 2.4	
Working Length (mm)		1050	1550
With Needle		NO	
Fenestrated Cups		YES	
Compatible Olympus Endoscopes (All of these parameters should be met.)	Model and Length	Working length less than 600 mm; OSF, BF	Working length less than 1100 r EF, GIF, O GF, GTF, CF (Exclu I-, L-length OSF, BF
	Channel Inner Diameter (mm) (Color Code)	ø 2.8, ø 3.2 (Yellow)	ø 2.8, ø 3 (Yellow ø 3.7, ø (Orange

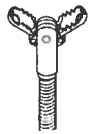
Model		FB-37K-1	FB-37U-1
Shape of the Cups		Rat Tooth 	
Maximum Insertion Portion Diameter (mm)		ø 2.4	
Working Length (mm)		1550	2300
With Needle		NO	
Fenestrated Cups		YES	
Compatible Olympus Endoscopes (All of these parameters should be met.)	Model and Length	Working length less than 1100 mm; EF, GIF, OGF, GF, GTF, CF (Exclude I-, L-length), OSF, BF	Working length less than 1850 mm; EF, GIF, OGF, GF, GTF, JF, TJF, SIF (SIF-10 only), CF, PCF, OSF, BF
	Channel Inner Diameter (mm) (Color Code)	ø 2.8, ø 3.2 (Yellow) ø 3.7, ø 6 (Orange)	ø 2.8, ø 3.2 (Yellow) ø 3.7, ø 4.2, ø 6 (Orange) ø 5.5 (Pink)

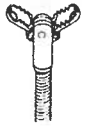
Model		FB-38W-1
Shape of the Cups		Rat Tooth 
Maximum Insertion Portion Diameter (mm)		ø 1.5
Working Length (mm)		2500
With Needle		NO
Fenestrated Cups		YES
Compatible Olympus Endoscopes (All of these parameters should be met.)	Model and Length	Working length less tha 2050 mm; CHF
	Channel Inner Diameter (mm) (Color Code)	ø 1.7 (Violet)

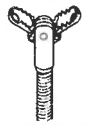
Model		FB-44D-1
Shape of the Cups		Standard Type 
Maximum Insertion Portion Diameter (mm)		ø 1.15
Working Length (mm)		1150
With Needle		NO
Fenestrated Cups		NO
Compatible Olympus Endoscopes (All of these parameters should be met.)	Model and Length	Working length less than 700 mm; CHF, BF, URF, HYF
	Channel Inner Diameter (mm) (Color Code)	ø 1.2, ø 1.5 (Not color coded)

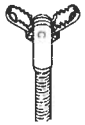
Model		FB-50K-1	FB-50Q-1
Shape of the Cups		Standard Type 	
Maximum Insertion Portion Diameter (mm)		ø 3.1	
Working Length (mm)		1550	1950
With Needle		YES	
Fenestrated Cups		YES	
Compatible Olympus Endoscopes (All of these parameters should be met.)	Model and Length	Working length less than 1100 mm; GIF	Working length less than 1500 m GIF, CF (I-length onl
	Channel Inner Diameter (mm) (Color Code)	ø 3.7, ø 6 (Orange)	ø 3.7, ø 4.2 ø 6 (Orange) ø 5.5 (Pink)

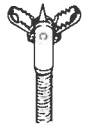
Model		FB-50U-1	FB-51K-1
Shape of the Cups		Standard Type 	
Maximum Insertion Portion Diameter (mm)		ø 3.1	ø 5.1
Working Length (mm)		2300	1550
With Needle		YES	
Fenestrated Cups		YES	
Compatible Olympus Endoscopes (All of these parameters should be met.)	Model and Length	Working length less than 1850 mm; GIF, TJF, CF	Working length less than 1100 mm; GIF-XT30 only
	Channel Inner Diameter (mm) (Color Code)	ø 3.7, ø 4.2, ø 6 (Orange) ø 5.5 (Pink)	ø 6 (Orange)

Model		FB-52C-1	FB-52K-
Shape of the Cups		Rat tooth with alligator jav (Swinging type) 	
Maximum Insertion Portion Diameter (mm)		ø 1.8	
Working Length (mm)		1050	1550
With Needle		NO	
Fenestrated Cups		YES	
Compatible Olympus Endoscopes (All of these parameters should be met.)	Model and Length	Working length less than 600 mm; CHF, BF, ENF, CYF, HYF, OSF	Working length less than 1100 n EF, GIF, OG GF, GTF, C CF (Exclud I-, L-length) OSF, BF, El CYF, HYF
	Channel Inner Diameter (mm) (Color Code)	ø 2, ø 2.2 (Blue) ø 2.6 (Green) ø 2.8, ø 3.2 (Yellow)	ø 2, ø 2.2 (Blue) ø 2.6 (Green) ø 2.8, ø 3. (Yellow) ø 3.7, ø 6 (Orange)

Model		FB-53K-1	FB-53Q-1
Shape of the Cups		Rat tooth with alligator jaws (Swinging type) 	
Maximum Insertion Portion Diameter (mm)		ø 2.4	
Working Length (mm)		1550	1950
With Needle		NO	
Fenestrated Cups		YES	
Compatible Olympus Endoscopes (All of these parameters should be met.)	Model and Length	Working length less than 1100 mm; EF, GIF, OGF, GF, GTF, CF (Exclude I-, L-length), OSF	Working length less than 1500 mm; EF, GIF, OGF, GF, GTF, JF, TJF, CF (Exclude L-length), PCF(I-length only), OSF
	Channel Inner Diameter (mm) (Color Code)	ø 2.8, ø 3.2 (Yellow) ø 3.7, ø 6 (Orange)	ø 2.8, ø 3.2 (Yellow) ø 3.7, ø 4.2, ø 6 (Orange) ø 5.5 (Pink)

Model		FB-53U-1	FB-54K-1
Shape of the Cups		Rat tooth with alligator jav (Swinging type) 	
Maximum Insertion Portion Diameter (mm)		ø 2.4	
Working Length (mm)		2300	1550
With Needle		NO	
Fenestrated Cups		YES	
Compatible Olympus Endoscopes (All of these parameters should be met.)	Model and Length	Working length less than 1850 mm; EF, GIF, OGF, GF, GTF, JF, TJF, SIF (SIF-10 only), CF, PCF, OSF	Working length less than 1100 m EF, GIF, OG GF, GTF, CI (Exclude I-, L-length), O
	Channel Inner Diameter (mm) (Color Code)	ø 2.8, ø 3.2 (Yellow) ø 3.7, ø 4.2, ø 6 (Orange) ø 5.5 (Pink)	ø 2.8, ø 3. (Yellow) ø 3.7, ø 6 (Orange)

Model		FB-54Q-1	FB-54U-1
Shape of the Cups		Rat tooth with alligator jaws (Swinging type) 	
Maximum Insertion Portion Diameter (mm)		ø 2.4	
Working Length (mm)		1950	2300
With Needle		NO	
Fenestrated Cups		YES	
Compatible Olympus Endoscopes (All of these parameters should be met.)	Model and Length	Working length less than 1500 mm; EF, GIF, OGF, GF, GTF, JF, TJF, CF (Exclude L-length), PCF(I-length only), OSF	Working length less than 1850 mm; EF, GIF, OGF, GF, GTF, JF, TJF, SIF (SIF-10 only), CF, PCF, OSF
	Channel Inner Diameter (mm) (Color Code)	ø 2.8, ø 3.2 (Yellow) ø 3.7, ø 6 (Orange)	ø 2.8, ø 3.2 (Yellow) ø 3.7, ø 4.2, ø 6 (Orange) ø 5.5 (Pink)

Model		FB-55K-1	FB-55Q-1
Shape of the Cups		Rat tooth with alligator jaw (Swinging type) 	
Maximum Insertion Portion Diameter (mm)		ø 2.4	
Working Length (mm)		1550	1950
With Needle		YES	
Fenestrated Cups		YES	
Compatible Olympus Endoscopes (All of these parameters should be met.)	Model and Length	Working length less than 1100 mm; EF, GIF, OGF, GF, GTF, CF (Exclude I-, L-length), OSF	Working length less than 1500 mı EF, GIF, OGI GF, GTF, JF, TJF, CF (Exclude L-length), PCF(I-length only), OSF
	Channel Inner Diameter (mm) (Color Code)	ø 2.8, ø 3.2 (Yellow) ø 3.7, ø 6 (Orange)	ø 2.8, ø 3.2 (Yellow) ø 3.7, ø 4.2 ø 6 (Orange) ø 5.5 (Pink)

Model		FB-55U-1
Shape of the Cups		Rat tooth with alligator jaws (Swinging type) 
Maximum Insertion Portion Diameter (mm)		ø 2.4
Working Length (mm)		2300
With Needle		YES
Fenestrated Cups		YES
Compatible Olympus Endoscopes (All of these parameters should be met.)	Model and Length	Working length less than 1850 mm; EF, GIF, OGF, GF, GTF, JF, TJF, SIF(SIF-10 only), CF, PCF, OSF
	Channel Inner Diameter (mm) (Color Code)	ø 2.8, ø 3.2 (Yellow) ø 3.7, ø 4.2, ø 6 (Orange) ø 5.5 (Pink)
Medical Device Directive	CE	This device complies with the requirements of Directive 93/42/EEC concerning medical devices. Classification: Class I

Chapter 3 Preparation, Inspection and Operation

WARNING

- Before each case, prepare and insp the instrument as instructed bel Inspect other equipment to be us with the instrument as instructec their respective instruction manu Should the slightest irregularity suspected, do not use the instrume contact Olympus.
  Damage or irregularity m compromise patient or user safe such as infection control risk, tiss irritation punctures, hemorrhages mucous membrane damage and n result in more-severe equipm damage.
- This instrument was not steriliz before shipment. Before using t instrument for the first time, reproc it according to the instructions Chapter 4, "Reprocessing".
  Do not use an instrument that has been cleaned and sterilized. T poses an infection control risk or c cause tissue irritation.
- When using an instrument that ha Needle, be careful not to touch t Needle. Infectious substanc attached to the Needle such as patient's blood or mucous, could pc an infection control risk and/or cau patient injury.

CAUTION

- Do not coil the Insertion Portion with a diameter of less than 15 cm. This could damage the Insertion Portion.
- Never use excessive force to open or close the Cups. This could damage the instrument.

3.1 Preparation

Equipment and Personal Protective Equipment

Prepare all equipment and personal protective equipment which will be used with the instrument in accordance with their respective instruction manuals. Appropriate personal protective equipment may include: Eye wear, a face mask, moisture-resistant clothing and chemical-resistant gloves.

Spare Instrument

Always have a spare instrument available.

Reprocessing Equipment

Prepare reprocessing equipment as described in Section 4.2, "Required Reprocessing Equipment" for immediate reprocessing after use.

3.2 Inspection

Wear the personal protective equipment as specified in t Table on page 49.

Before each case, always inspect the instrume according to the following procedures.

If an abnormality in the instrument is detected, use a spa instrument, inspecting it thoroughly before use.

Inspection of the Sterile Package

Inspect the sterile package for tears, inadequate seali or water damage. If the sterile packages shows a irregularities, the sterile condition of the instrument h been compromised. Use a spare instead.

Appearance Inspection

If any of following steps reveals irregularities, do not u the instrument; use a spare instead.

1. While operating the Slider to open and close the Cu confirm that the instrument is free from disconnecti or looseness.
2. Make sure that the Cups close evenly and a properly aligned when the Slider is pulled.
3. When using an instrument with a Needle, push t Slider to open the Cups and confirm that the Neec is not detached or bent conspicuously.
4. Confirm that the Distal End of the instrument appea exactly as shown in the Tables in Section 2 "Specifications" and is not damage.
5. Gently run your fingertips over the entire length of t Insertion Portion to check for any crushed area excessive bends, etc.

6. Make sure that there are no cracks on tne Handle.

Inspection of Operation

If the Cups do not operate smoothly and as intended, do not use the instrument; use a spare instead.

1. Holding the instrument as shown in Figure 3.1, form a loop in the Insertion Portion approximately 20 cm in diameter.

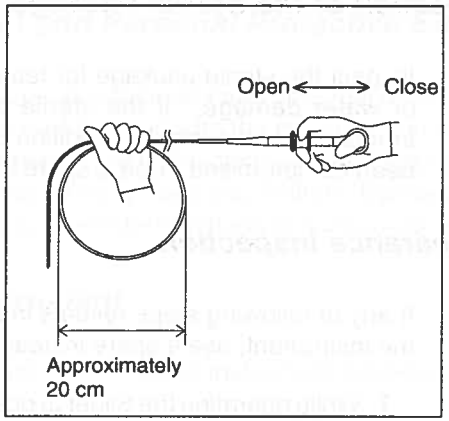


Figure 3.1

2. Move the Slider and confirm that the Cups open and close smoothly.

3.3 Operation

The operator of the 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. It only describes basic operation and precautions related to the operation of this instrument.

WARNING

- When using the instrument, alwa wear appropriate personal protecti equipment. Otherwise, bloo mucous and other potentia infections material from the patie could pose an infection control ris Appropriate personal protecti equipment may include: Eye wear, face mask, moisture-resistant clothi and chemical-resistant gloves that properly and are long enough so th your skin is not exposed.
- Do not insert the instrument into tl endoscope unless you have a cle endoscopic field of view. If you cann see the Distal End of the Insertic Portion in the endoscopic field of vie or in X ray images, do not use it. Tl could cause patient injury, such a punctures, hemorrhages or mucoı membrane damage. It may als damage the endoscope and/ instrument.
- Do not angulate the Bending Sectic of the endoscope(or operate tl Forceps Elevator if applicabl abruptly while the Distal End of tl Insertion Portion is extended from tl Distal End of endoscope. This cou cause patient injury, such a: punctures, hemorrhages or mucoı membrane damage.

CAUTION

When using the instrument with a tw channel endoscope, never us electrosurgical accessories at the sam time. This could cause patient, operat or assistant injury, such as thermal injur

Inserting Into the Endoscope

WARNING

- Do not force the instrument if resistance to insertion is encountered. Reduce the angulation (or lower the Forceps Elevator if applicable) until the instrument passes smoothly. This could cause patient injury, such as punctures, hemorrhages or mucous membrane damage. It may also damage the endoscope and/or instrument.
- When inserting the instrument into the endoscope, hold the Slider firmly. Otherwise, the Cups may open and extend from the endoscope tip abruptly. This could cause patient injury, such as punctures, hemorrhages or mucous membrane damage. It may also damage the endoscope and/or instrument.
- Do not advance or extend the instrument abruptly. This could cause patient injury, such as punctures, hemorrhages or mucous membrane damage. It may also damage the endoscope and/or instrument.

CAUTION

- When inserting the instrument into the endoscope, hold it close to the Biopsy Valve or T-plug and keep it as straight as possible relative to the Biopsy Valve or T-plug. Otherwise, the Insertion Portion could be damaged.
- Before inserting the FB-51K-1 into the Biopsy Valve, open the Biopsy Valve. If you insert it without opening the Biopsy Valve, you may damage the Biopsy Valve and/or the instrument.

- When inserting the FB-51K-1 into t Biopsy Valve, hold it near the Dis End of the Insertion Portion to av damaging the instrument.

Combined With non-GF, non-GTF, non-, or non-TJF Endoscopes

1. Pull the Slider to close the Cups.
2. With the Cups closed, carefully insert the instrum into the Biopsy Valve or T-plug. (See Figure 3.2)

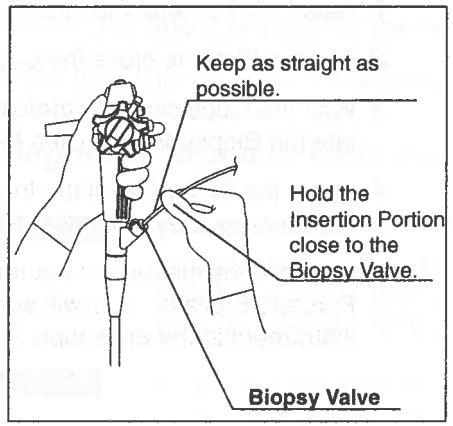


Figure 3.2

3. Advance the instrument until the Distal End of t Insertion Portion appears within the endoscopic fi of view.

❍ Combined With GF, GTF, JF or TJF Endoscopes

WARNING When inserting the instrument into GF, GTF, JF or TJF endoscopes, raise the Forceps Elevator to its maximum height. If the Forceps Elevator is down, you will not be able to see the Distal End of the Insertion Portion in the endoscopic field of view. This could cause patient injury, such as punctures, hemorrhages or mucous membrane damage.

1. Raise the Forceps Elevator to its maximum height.
2. Pull the Slider to close the Cups.
3. With the Cups closed, carefully insert the instrument into the Biopsy Valve. (See Figure 3.2)
4. When the Distal End of the Insertion Portion contacts the Forceps Elevator, lower the Forceps Elevator.
5. Advance the instrument another 20 mm and raise the Forceps Elevator. You will see the Distal End of the instrument in the endscopic field of view.

Collecting Tissue

WARNING Do not force the Distal End of the Inserti Portion against body cavity tissue. T could cause patient injury, such punctures, hemorrhages or muco membrane damage.

1. To collect the target tissue, angulate the Bendi Section or advance the instrument until it reaches t target site.
2. Push the Slider to open the Cups.
3. Press the open Cups against the target tissue.
4. Pull the Slider to collect the target tissue.

Withdrawing the Instrument From the Endoscop

WARNING Do not withdraw the instrument from t endoscope quickly. This could scat blood, mucous or other patient debris a pose an infection control risk.

CAUTION
- Do not withdraw the instrument fr the endoscope while the Cups a open. This could damage t endoscope and/or instrument.
- If excessive resistance mak withdrawal difficult, adjust the angle the endoscope until the instrument c be withdrawn smoothly. Forcib withdrawal could damage t instrument and/or endoscope.

1. If the endoscope is equipped with a Forceps Elevat lower the Forceps Elevator.
2. Pull the Slider to close the Cups.
3. Withdraw the instrument from the endoscope.

Chapter 4 Reprocessing

WARNING This instrument was not sterilized before shipment. Before using this instrument for the first time, reprocess it according to the instructions in this Chapter. Do not use an instrument that has not been cleaned and sterilized. This poses an infection control risk or can cause tissue irritation.

4.1 General Policy

- The medical literature reports incidents of patient cross contamination resulting from improper cleaning or sterilization. It is strongly recommended that reprocessing personnel have a thorough understanding of and follow all national and local hospital guidelines and policies.
  A specific individual or individuals in the endoscopy unit should be responsible for reprocessing endoscopic equipment. It is highly desirable that a trained backup be available should the primary reprocessing individual(s) be absent.
- All individuals responsible for reprocessing should thoroughly understand:
  - your institution's reprocessing procedures
  - occupational health and safety regulations
  - national and local hospital guidelines and policies
  - the instructions in this manual
  - the mechanical aspects of endoscopic equipment

  - pertinent germicide labeling

Olympus Endo-Therapy Accessories are compatible w 2.0% to 3.2% glutaraldehyde solution. However, routi biological monitoring is not feasible with glutaraldehy and, therefore, it should not be used to sterilize reusat medical devices that are compatible with other methods sterilization that can be biologically monitored, such steam sterilization.

WARNING

- Failure to properly clean and sterili the instrument after each examinati can compromise patient safe During use, the instrument norma comes in contact with intact muco membranes. To minimize the risk transmitting diseases from one patie to another, after each examination tl instrument must undergo thorou cleaning followed by sterilization.
- If the instrument is not cleane meticulously, effective sterilizati cannot be obtained. Clean tl instrument thoroughly befo sterilization to remo microorganisms or organic mater which can limit the effectiveness of tl sterilization process.

- Patient debris and reprocessing chemicals are hazardous. Wear personal protective equipment to guard against dangerous chemicals and infectious material. During cleaning and sterilization, always wear appropriate personal protective equipment, such as eye wear, a face mask, moisture-resistant clothing and chemical-resistant gloves that fit properly and are long enough so that your skin is not exposed. Always remove contaminated protective clothing before leaving the reprocessing area.
- The reprocessing procedures described in this manual should be completed the same day has been used. If reprocessing is delayed, residual organic debris will solidify and it may be difficult to effectively reprocess the instrument.

4.2 Required Reprocessing Equipment

Wear the personal protective equipment as specified in the Table on page 49.

1. Prepare the following equipment. The required amount of detergent solution, lubricant and other equipment depends on the number of instruments to be reprocessed.
2. Fill an immersion basin with detergent solution and fill a second immersion basin with lubricant at the temperatures and concentrations recommended by the manufacturers. Also fill the ultrasonic cleaner with a detergent solution appropriate for ultrasonic cleaning.

Equipment Needed for Reprocessing

To perform proper reprocessing, the equipment in t following Table is required. For details on preparation a directions for use of the following equipment, refer to t respective instruction manuals or contact the equipme manufacturer.

Contact Olympus for the names of specific brands detergent solutions and lubricants.

Equipment Needed

Protective Equipment	Appropriate personal protective equipment may include: Eye wear, face mask, moisture-resistant clothing and chemical-resistant gloves.
Immersion Basin for Detergent Solution	Use a basin with a depth and diameter larg enough to allow complete immersion of the instrument when the Insertion Portion is coiled with a diameter of not less than 15 cr
Detergent Solution for Immersion	Use a neutral pH, low-foaming, medical grade detergent solution.
Ultrasonic Cleaner	Use a medical grade ultrasonic cleaner witl a frequency range of 38 to 47 kHz, and witl a depth and a diameter large enough to allo complete immersion of the instrument whe the Insertion Portion is coiled with a diamet of not less than 15 cm. Compatible ultrasonic cleaners include OLYMPUS ULTRASONIC CLEANER KS-2
Detergent Solution for Ultrasonic Cleaning	Use a neutral pH, low-foaming, medical grade detergent solution with no abrasive.
Lubricant	Use a medical grade water soluble or low-viscosity emulsion type lubricant.

Immersion Basin for Lubricant	Use a basin with a depth and diameter large enough to allow complete immersion of the instrument when the Insertion Portion is coiled with a diameter of not less than 15 cm.
Lint-free Cloths	
Packages for Steam Sterilization	Use a packages compatible with steam sterilization (autoclaving). The packages should be large enough to accommodate the instrument when the Insertion Portion is coiled with a diameter of not less than 15 cm.
Sealing Device for packages	Sealing the packages may require a device such as a heat sealer. Prepare an appropriate searing device according to the packages to be used.
Autoclave	Use an autoclave that will operate at the conditions specified in Section 4.5, "Sterilization".

4.3 Cleaning

WARNING When cleaning, avoid exposure to the reprocessing chemicals. It may pose an infection control risk or cause skin irritation.

CAUTION

- When reprocessing, do not coil the Insertion Portion with a diameter of less than 15 cm. This could damage the Insertion Portion.
- Never use excessive force to open or close the Cups. This could damage the instrument.

Immersion

WARNING Immerse the instrument in deterge solution immediately after use. If t instrument is not cleaned immediately may be difficult to effectively reproce and this could result in reduc performance.

1. When reprocessing the instrument for the first ti after purchase, remove the Forceps Cap from t Cups and dispose of it.
2. Immerse the entire instrument in the deterge solution for the time specified in manufacture instructions. If no time is specified, immerse between 5 minutes and 3 hours.
3. Remove the instrument from the detergent solutio

Ultrasonic Cleaning

1. Immerse the entire instrument in the ultrasor cleaner containing detergent solution.
2. Clean ultrasonically for 30 minutes. For details operation of the ultrasonic cleaner, refer to t instruction manual of the ultrasonic cleaner.
3. Remove the instrument from the detergent solutio

Rinsing

CAUTION

- After ultrasonic cleaning, rinse t instrument thoroughly to remo residual detergent. Residu detergent solution could cause tiss irritation in the next patient.

- Do not forcefully squeeze, wipe or scrub the instrument. This could cause damage to the instrument or result in reduced performance.

1. Rinse the instrument under clean running tap water.
2. Confirm that no debris is left on the surfaces of the instrument.
3. Wipe the exterior of the instrument with a clean, dry lint-free cloth.

4.4 Lubrication

WARNING When lubricating, avoid exposure to the lubricant. It may pose an infection control risk or cause skin irritation.

CAUTION

- Do not coil the Insertion Portion with a diameter of less than 15 cm. This could damage the Insertion Portion.
- Never use excessive force to open or close the instrument. This could damage the instrument.

1. Immerse the Insertion Portion in the lubricant for 2 to 3 seconds.
2. Remove the instrument from the lubricant.
3. Operate the Slider to open and close the Cups two or three times.
4. Wipe the exterior of the instrument with a clean, dry lint-free cloth and allow the instrument to air dry.

4.5 Sterilization

Sealing the Package

WARNING Before placing the instrument in package, always close the Cu Otherwise they could tear the pack during sterilization or storage a compromise its sterility, which could p an infection control risk or cause tis irritation.

CAUTION

- Do not coil the Insertion Portion wi diameter of less than 15 cm. T could damage the Insertion Portio
- Never use excessive force to ope close the Cups. This could dam the instrument.

1. Before sterilization, the instrument must thoroughly cleaned and dried. Residual moist inhibits sterilization.
2. Coil the Insertion Portion and place the instrumer the package.
3. Seal the package. For details on sealing, refer to instruction manual of the package and the sea device.

Steam Sterilization (Autoclaving)

WARNING

- Use biological indicator recommended by your hospita policy and follow the manufactur instructions, all national and lo hospital guidelines, and policies.

- Always leave space between the packages in the autoclave. If the packages are placed too close together, effective sterilization will not be possible.
- Allow the packages to dry within the autoclave using the autoclave's drying cycle (if applicable) or by opening the door of the autoclave and allowing the packages to air dry. Handling a wet package can compromise its sterility.

1. Place the sealed package containing the instrument in the autoclave and sterize in accordance with the conditions listed below. For details on operation of the autoclave, refer to the instruction manual for the autoclave or other manufacturer instructions.
2. After steam sterilization, let the instrument gradually cool down to room temperature. Sudden changes in temperature may damage the instrument.

NOTE Autoclavable products have a green reference label. Products that do not have green reference labels are not autoclavable.

	Temperature	Exposure Time
Prevacuum	132 to 134°C (270 to 274°F)	5 minutes

Table 4.1 Recommended Steam Sterilization(Autoclaving) Conditions

Chapter 5 Storage

WARNING

- Do not store the instrument in a ste package that is damaged, wet improperly sealed. Otherwise, t sterility of the instrument may compromised and pose an infecti control risk or cause tissue irritatior
- Do not store the sterile packag containing the instrument in pla where they will be damaged, wet improperly sealed. Otherwise, t sterility of the instrument may compromised and pose an infecti control risk or cause tissue irritatior

CAUTION Do not coil the Insertion Portion witr diameter of less than 15 cm. This cou damage the Insertion Portion.

5.1 Inspection Before Storage

Prior to storage, inspect the sterile package as follows:

Confirm that the sterile package containing the instrume is free from tears, inadequate sealing or water damag If tears, inadequate sealing or water damage is detecte repackage and sterilize again as described in Section 4 "Sterilization".

5.2 Storage

Store the instrument in the sterile package at room temperature in a clean and dry environment. Do not store it in direct sunlight. Ensure that the packaged instrument is not crushed by surrounding objects during storage. Follow any additional storage instructions provided by the manufacturer of the sterile package.

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