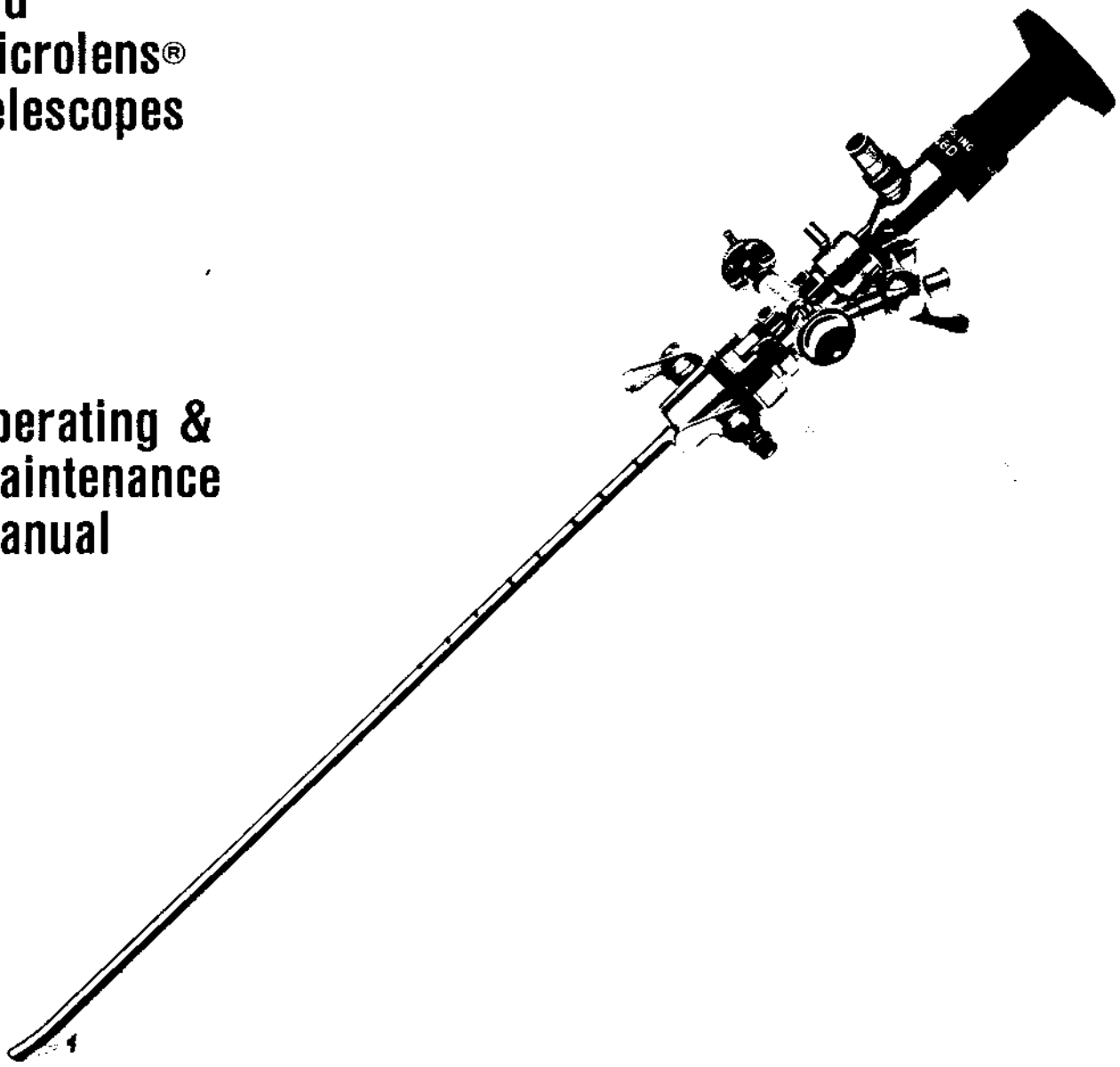
American ACMI

Cystourethroscope and Microlens® Telescopes



Operating & Maintenance Manual

American ACMI

Cystourethroscope
and
Microlens®
Telescopes

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Cautions

The following cautions apply to the use, care and/or maintenance of urological endoscopic instruments and accessories.

1. Study this manual and other accompanying labeling carefully and thoroughly before handling endoscopic instruments or accessories. Retain in a convenient, readily-accessible place for reference when needed.

2. Endoscopic instruments should be handled with care by informed personne completely familiar with their assembly, operation and disassembly. They are precision instruments which can be damaged by misuse or abuse.

3. Perform the prescribed inspections and operational tests prior to first use, and regularly thereafter to assure continued satisfactory performance.

4. Procedures with endoscopic instruments should be performed only by persons with adequate training and preparation. Consult the medical literature regarding techniques, complications and hazards prior to any endoscopic procedure.

5. Thoroughly know the specific endoscopic instruments being used. Each instrument is different in the nuances of motion and feel. Such knowledge is essential to avoid hazards to the patient, the operator and the instruments.

6. Consult the operating manuals for light sources, electrosurgical units and other ancillary devices for appropriate instructions and cautions prior to their use with endoscopic instruments. When endoscopic instruments and accessories from different manufacturers are used together, verify that any isolation or grounding is not violated.

7. Clean endoscopic instruments thoroughly prior to disinfection or sterilization processes. Use warm water only. Hot water can alter organic material making it difficult to remove. Do not disassemble instruments beyond that described in the labeling. Do not use ultrasonic cleaners which can damage precision joints and seals.

8. Follow disinfectant or sterilizer manufacturer's recommended procedures and cautions to avoid patient hazards and instrument damage. Do not autoclave endoscopic instruments or accessories unless this modality is specifically cited as permissable in the labeling.

9. Follow the labeling instructions for the safe handling and storage of endoscopic instruments. Improper storage can damage instruments.

10. Thoroughly understand the nature and use of radio frequency (RF) currents before performing endoscopic electrosurgical procedures. This understanding is essential to avoid shock and burn hazards to both patient and operator, and damage to instruments.

11. If a larger than normal electrosurgical unit power setting is required during any endoscopic electrosurgical procedure, stop. Do not increase power setting until all instruments, connections, cables and patient contacts have been checked and appear fault-free. Increase power settings in small increments, checking the change in effect after each increase.

12. Avoid using conductive tubing with endoscopic instruments. Such tubing can increase the risk of shocks and burns, particularly during endoscopic electrosurgical procedures.

13. Use surgical gloves designated by their manufacturers for endoscopic electrosurgical procedures. The use of other gloves can result in burns or shock.

14. Follow the labeling instructions regarding the disposal or reuse of endoscopic instrument accessories after each procedure. The stresses applied to some instruments during a procedure can not be assessed; and reuse of such instruments could compromise patient safety.

15. During endoscopic electrosurgical procedures, prevent small conductive areas such as stopcock handles from touching the patient. The current density of normal RF leakage currents can be sufficient to burn when the contact area is very small.

16. Use only those lubricants and replacement parts specified in the labeling. The use of other items can compromise patient and operator safety.

17. Be sure to store bridges with storage rod in place at all times, especially when bridge is laid on the O.R. instrument table.

18. Prior to each use, the cystoscopic electrode and its insulating tube should be examined for splits, cracks, holes, burn marks or any other imperfections.

19. Always remove the bridge and telescope together when removing from the sheath. This will help prevent damage to the telescope guide tube of the bridge.

20. When cleaning bridges, always insert cleaning brush through the telescope lock opening; never through the distal end.

21. When using the bridges, always hold them at their proximal end, particularly during cleaning.

22. The Microlens Telescope is a precision optical device and should be handled with care. Avoid mechanical shock such as will occur if the instrument is dropped, or if another object strikes it.

23. Do not loosen or remove the telescope eyepiece at its proximal end as this can break the seal causing leakage.

24. Microlens Telescope should be maintained separate from other instruments during storage, cleaning, disinfecting, etc. Haphazard mixing of these telescopes with other instruments increases the risk of damage.

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1.0 Unpacking and Initial Inspection

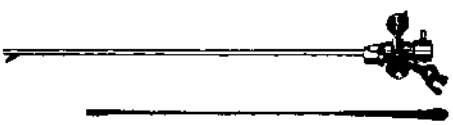
To avoid inadvertent damage, study the operating and maintenance Manual thoroughly before handling instrument. Visually examine the shipping carton instrument case, instruments and accessories for signs of shipping damage. Any breakage or other apparent damage should be noted, the evidence retained, and the carrier or shipping agency contacted.
In case of discrepancy, notify the ACMI sales representative or ACMI Customer Service immediately.

2.0 General Description

The ACMI Adult Cystourethroscope set is a complete system with a color-coding feature, enabling components to be combined quickly and easily, minimizing error or confusion. This complete system has been designed to be adaptable to the older ACMI Wappler Cystourethroscope system. (Refer to ACMI compatability chart.)

*G117 Sheath and Obturator 17 Fr red
*G121 Sheath and Obturator 21 Fr orange
*G123 Sheath and Obturator 23 Fr yellow
*G125 Sheath and Obturator 25 Fr green

*G161 Visual Obturator 21 Fr orange
*G163 Visual Obturator 23 Fr yellow
*G165 Visual Obturator 25 Fr green



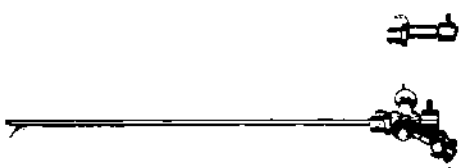
*G151 Double Catheterizing Albarran Bridge for 20 & 21 Fr sheaths w/ storage rod: orange

*G152 Double Catheterizing Albarran Bridge for 22 through 25 FR Sheaths with DC Fin (G162) and storage rod: yellow/green

*G162 Double Catheterizing Fin for G152.

G153 Short Bridge for 17-25 Fr sheaths

G164 Stationary Deflector for G153 (only to be used with 23-25 Fr sheaths)



G154 Examining Bridge for 17-25 Fr Sheaths

*G155 Operating Albarran Bridge for 22 through 25 Fr Sheaths with storage rod: yellow/green

*G156 Operating Cawood Deflecting Bridge for 22 through 25 Fr sheaths with storage rod: yellow/green

*G157 Double Catheterizing Cawood Deflecting Bridge for 20 and 21 Fr sheaths with storage rod: orange

*G158 Double Catheterizing Cawood Deflecting Bridge for 22 through 25 Fr sheaths with storage rod (The G162 Double Catheterizing Fin can be used on a G158): yellow/green

FO-8168D Microlens® Direct Viewing Telescope 0° angle of view
FO-8168M Microlens® Foroblique Telescope 30° angle of view
FO-8168L Microlens® Lateral Telescope 70° angle of view
FO-8168R Microlens® Retrospective Viewing Telescope 120° angle of view

*Color coded

3.0 Operation

3.1 Instrument Preparation

1. Assemble instruments as needed for procedure.

2. Perform operational inspection and tests according to procedures in Section 5.0 of this manual.

3.2 Color Coding

The Cystourethroscope sheaths have been color coded for easy identification.

Nominal French Size	Color
17	Red
21	Orange
23	Yellow
25	Green

3.3 Telescope Bridge Lock

1. Remove storage rod from bridge (if applicable).

2. Insert telescope into bridge. Be sure telescope guide pin and rotating collar of bridge are both facing upward. Seat telescope into bridge.

3. Firmly rotate collar clockwise until telescope is firmly locked.

4. Always insert telescope into bridge before inserting into sheath.

5. If telescope is difficult to slide into bridge, place a dab of PETE lubricating paste (G925) on seal.

CAUTION: Collar should be firmly locked or the telescope may loosen during procedures.

3.4 Sheath Lock

1. Assemble telescope and bridge as described in Section 3.3.

2. Insert assembled telescope/bridge into sheath. Be sure key pins on bridge are lined up with sheath lock slots.

3. When bridge is firmly seated into sheath, turn rotating collar clockwise until securely in place.

3.5 Disassembly/ Assembly of Double Catheterizing Fin

1. Hold base of bridge in one hand. Place a fingernail on the slot on the fin's vertical wall and slide the fin forward. See Figure 1.

2. Remove storage rod.

3. Twist the fin slightly to disengage the clips from the guide wire tube. (Be careful not to bend the clips.)

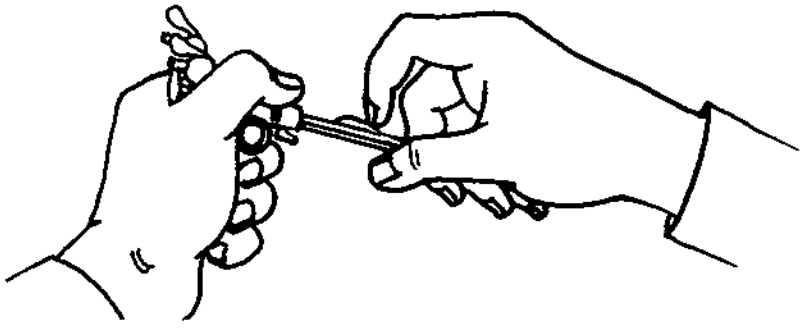


Figure 1

1. To assemble, slide the proximal end of the fin into the head of the bridge. Notice a "thin groove" in the head of the bridge into which the fin must be inserted.

2. Snap clips onto guide wire tubes. (Be careful not to bend the clips.)

3. Insert storage rods prior to storage.

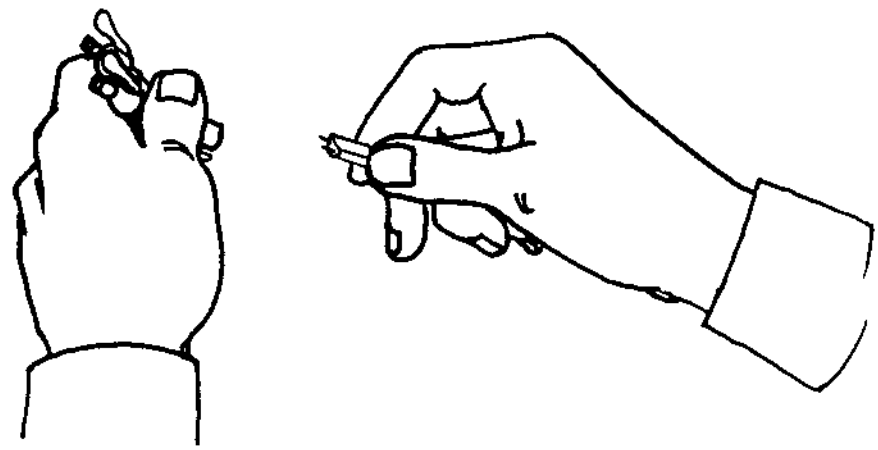
3.6 Disassembly/ Assembly of Stationary Deflector

1. To disassemble,

2. Grasp the shaft of the short bridge with fingers. With other hand, pull at base of deflector shaft to disengage from short bridge. See Figure 2.

3. To assemble, place bridge in one hand with stopcocks facing upward. With hollow tube facing upward, line up pins on stationary deflector. Insert deflector into bridge until secure.

Figure 2



3.7 Catheters, Forceps, Electrodes

The following chart illustrates the maximum thruput capacity for catheters, forceps, and electrodes. "Insertion" refers to inserting one (or two) catheters, and electrode or forceps with the bridge already in place. "Withdrawal" refers to withdrawing the bridge and leaving the one (or two) catheters in place.

CATHETER CAPACITY OF ACMI CYSTOURETHROSCOPE

		SHORT BRIDGE			CATHETERIZING BRIDGE	
SHEATH SIZE	NUMBER OF CATH.	W/O STATION DEFL.	W/STATION DEFL.	OPER. BRIDGE	W/O DC FIN	W/DC FIN
17	2	4 Fr	*	*	*	*
	1	5 Fr	*	*	*	*
21	2	6 Fr	*	*	6 Fr	*
	1	9 Fr	*	*	8 Fr	*
23	2	8 Fr	8 Fr	*	7 Fr	6 Fr
	1	11 Fr	11 Fr	11 Fr	11 Fr	6 Fr
25	2	8 Fr	8 Fr	*	8 Fr	7 Fr
	1	12 Fr	12 Fr	12 Fr	12 Fr	8 Fr

* Not Applicable

3.8 Interchangeability of G-Series with Wappler Cystoscopes

Wappler Series	New G-Series	Color Code	Sheath ACMI Catalogue No.	Visual Obturators	Catheterizing Bridges	Operating Bridge	Short Bridge	Examining Bridge
17Fr			(#8210)*				(81884)* GA153 w/O G164	G154
	17Fr	Red	G117				(81884)* G153 w/O G164	G154
20Fr			(#8187)	(8202)	(8200)* G151 G157		(81884)* G153 w/O G164	G154
	21Fr	Orange	G121	G161	(8200)* G151 G157		(81884)* G153 w/O G164	G154
22Fr			(#8182)	(8203)	(8200A)* G152 G158	G155 G156	(81884)* G153 w/G164	G154
	23Fr	Yellow	G123	G163	(8200A)* G152 G158	G155 G156	(81884)* G153 w/G164	G154
24Fr			(8195)*	(8204)	(8200A)* G152 G158	G155 G156	(81884)* G153 w/G164	G154
	25Fr	Green	G125	G165	(8200A)* G152 G158	G155 G156	(81884)* G153 w/G164	G154

[Wappler Instrument No.]
*No Longer Available
Note: McCarthy Panendoscope may use Microlens® telescope in conjunction with 150M Bridge.

4.0 Operational Tests

1. Before first use and before each procedure, inspect all components.

2. Examine the Microlens® Telescope for optical quality. If necessary, clean outside of proximal and distal lenses with a cotton applicator saturated with 70% isopropyl alcohol. Do not wipe the lettering of the telescope eyepiece with alcohol. Do not use if vision remains distorted or cloudy after cleaning.

3. Check proper alignment of sheath in telescope. The sheath may be partially visible in the telescope field when in air, but not in water.

4. Visually inspect the entire surface of the sheaths and obturators for any dents, protrusions, or other irregularities. Pass entire shaft through hand checking for any irregularities or sharpness.

5. Be sure that all rotating collar locks fasten telescope or bridges securely.

6. Open and close stopcock several times insuring smooth action.

7. Check deflecting action of Albarran or Cawood bridges for smoothness. Be sure the shaft does not appear to be bent.

5.0 Cleaning, Disinfecting, Sterilization

5.1 Cleaning

After each use or prior to placing in a disinfectant or sterilizer, perform the following:

1. Separate any assembled components. Soak all components thoroughly in a solution of protein bound soap and warm tap water. Do not use hot water as it will coagulate organic materials.

2. Open the stopcocks to clean. Use a soft brush to loosen and remove dried debris and excess lubricant.

3. Scrub sheaths, bridges, and obturators with a soft brush paying careful attention to the catheter guides and the lumen of the sheaths.

4. Rinse all components thoroughly in warm tap water.

5. Towel dry.

1. Keep the telescopes separate from other components when cleaning.

2. Wash in a solution of protein bound soap and warm tap water with a soft brush or sponge. Do not use hot water as it will coagulate organic materials.

3. Rinse thoroughly in warm tap water.

4. Towel dry thoroughly.

5. Clean outside of proximal and distal lenses with a cotton applicator saturated with 70% isopropyl alcohol.

Note: The Microlens telescope, as all precision optical devices, should be handled with care. Avoid:
a) Excessive immersion time in disinfectant.
b) Loosening or removing the eyepiece.
c) Laying heavy objects on the telescope.
d) Dropping.

5.2 Disinfection

1. Be sure all components have been properly cleaned prior to disinfection procedure.

2. Use only a plastic or enamel tray for disinfection.

3. Components can be immersed in 2% activated gluteraldehyde (alkaline) in accordance with disinfectant manufacturer's recommendations and instructions. Do not immerse telescopes in excess of 30 minutes.

4. Rinse components thoroughly in a basin of sterile water, as chemical contained in disinfecting solutions can cause electrical problems if not thoroughly rinsed.

5. Towel dry thoroughly.

5.3 Sterilization

1. Be sure all components are properly cleaned prior to sterilization.

2. All components of the Adult Cystourethroscope system can be placed in an ethylene oxide sterilizer whose parameters do not exceed the following:
Temperature: 145° F (maximum)
Vacuum: 28 inches Hg (maximum)
Pressure: 12 psi (maximum)

3. After ethylene oxide exposure, aerate the components in accordance with sterilizer maufacturer's instructions for surgical instruments.

4. All components of the cystourethroscope, except the Microlens telescope can be placed in a steam autoclave whose parameters are controlled as follows:
Temperature: 275° F (maximum)
Time: 20 minutes (maximum)

6.0 Storage

When not in use, store cystourethroscope components in a clean, dry cabinet. Keep instruments separate from one another to prevent nicking and scratching of finish.

7.0 General Care

All the components in the Adult Cystourethroscope system are precision instruments and should be handled with care.

1. Avoid handling more than one instrument at a time, or piling instruments on top of another.

2. Avoid excessive bending of instruments, especially visual obturators and Albarran/ Cawood bridges.

3. Do not loosen or remove the eyepiece from the telescope. Seal will be broken causing leakage and damage.

To avoid tarnish or corrosion of instruments:

1. Follow cleaning instructions in Section 5.0 of this manual.

2. Avoid the use of metal trays for soaking as this will cause electrolytic action and staining.

3. Avoid excessive immersion times.

4. Avoid high acid, chlorinated and phenol disinfectants as they can deteriorate some materials used in these instruments.

5. Towel dry instruments thoroughly to prevent the possibility of rusting.

6. Instruments may be polished with a non-abrasive commercial metal polish.

7.1 Stopcock Care

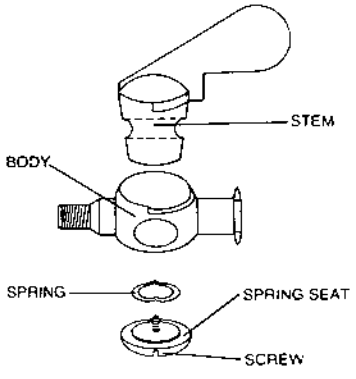


Figure 3

Under normal use, the lubricant in the stopcock when received from ACMI will provide long term lubricity. Routinely relubricate the stopcock as described below:

1. Remove screw at base of stopcock with screwdriver.

2. Be careful to avoid scratching tapered surfaces.

3. Clean all components with a cotton applicator saturated with 70% isopropyl alcohol.

7.1 Stopcock Care (Continued)

4. With an applicator, coat surface of stem, body and spring seat liberally with silicone lubricant, ACMI Catalog No. G925.
5. Insert stem in body and rotate two or three times to squeeze out excess lubricant.
6. Assemble spring, insert and tighten screw carefully until it stops. Do not force or overtighten.
7. Wipe excess lubricant from outside surfaces.

Kit List and Components

The following chart details each component in the Adult Cystourethroscope systems and the components supplied in each kit.

COMPONENTS	Kit Catalog Number G80	G81	G82	G83	G84	G85	G86	G87
*G117 Sheath and Obturator 17 Fr			X	X	X	X		
*G121 Sheath and Obturator 21 Fr	X	X	X	X	X	X	X	X
*G123 Sheath and Obturator 23 Fr			X	X			X	X
*G125 Sheath and Obturator 25 Fr	X	X	X	X				
*G161 Visual Obturator 21 Fr			X	X				
*G163 Visual Obturator 23 Fr			X	X				
*G165 Visual Obturator 25 Fr			X	X				
*G151 Double Catheterizing Albarran Bridge for 20 and 21 Fr sheaths w/storage rod	X	X	X	X	X	X	X	X
*G152 Double Catheterizing Albarran Bridge for 22-25 Fr sheath w/storage rod	X	X	X	X			X	X
G162 Double Catheterizing Fin for G152	X	X	X	X			X	X
G153 Short Bridge for 17-25 Fr Sheaths	X	X	X	X	X	X	X	X
G164 Stationary Deflector for G153			X	X				
G154 Examining Bridge for 17-25 Fr Sheaths	X	X	X	X	X	X	X	X
*G155 Operating Albarran Bridge for 22-25 Fr sheath w/storage rod	X	X	X	X				
*G156 Operating Cawood Deflecting Bridge for 22 through 25 Fr sheaths w/storage rod								
*G157 Double Catheterizing Cawood Deflecting Bridge for 20 and 21 Fr sheaths w/storage rod								
*G158 Double Catheterizing Cawood Deflecting Bridge for 22 through 25 Fr sheaths w/storage rod								
FO-8168M Microlens® Foroblique Telescope	X		X		X		X	
FO-8168L Microlens® Lateral Telescope			X					
FO-8168D Microlens® Direct Viewing Telescope								
FO-8168R Microlens® Retrospective Viewing Telescope								
96B set of Accessories	X	X	X	X	X	X	X	X
ACM44 Case	X	X	X	X	X	X	X	X

*color coded