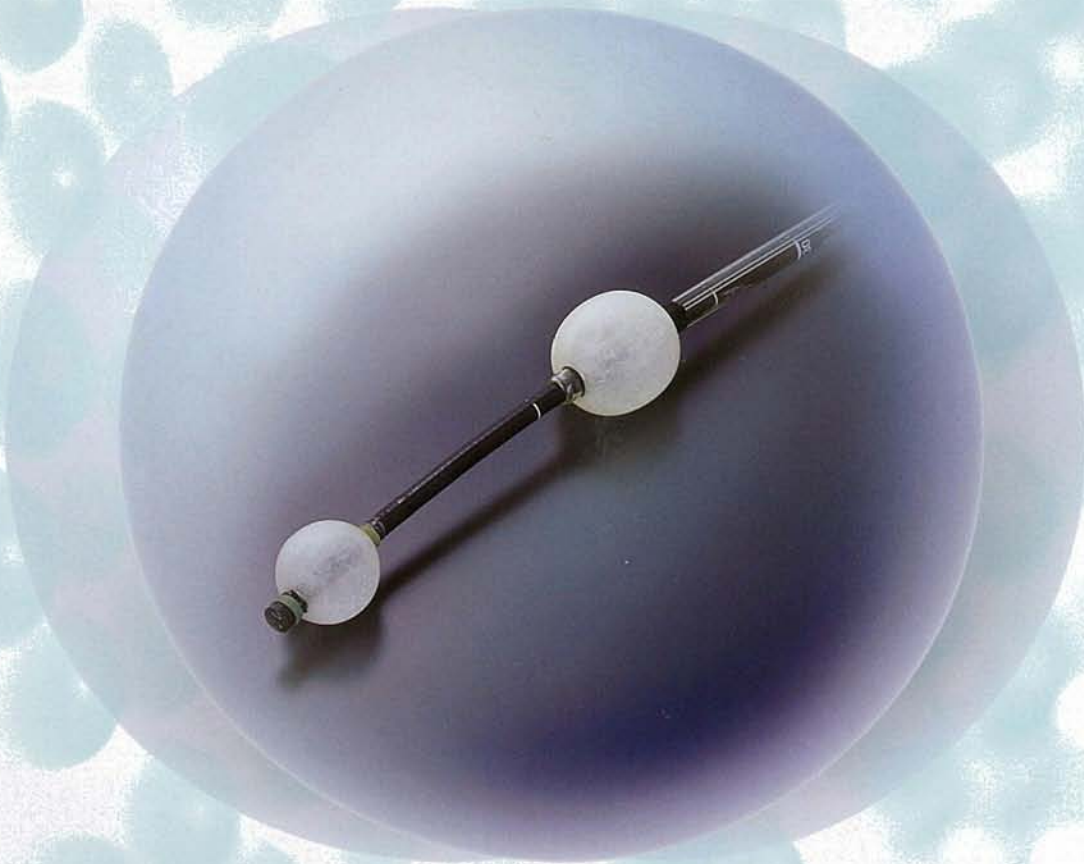


 **DOUBLE BALLOON
ENDOSCOPY**

Double Balloon Endoscopy System



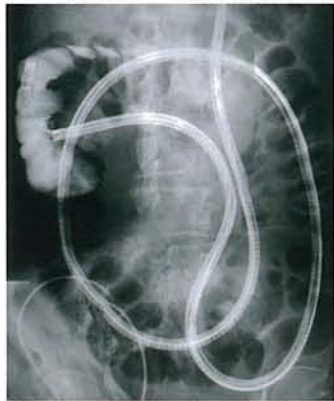
FUJINON
FUJIFILM

Double Balloon Endoscopy : An innovative that redefines Small Bowel intervention.

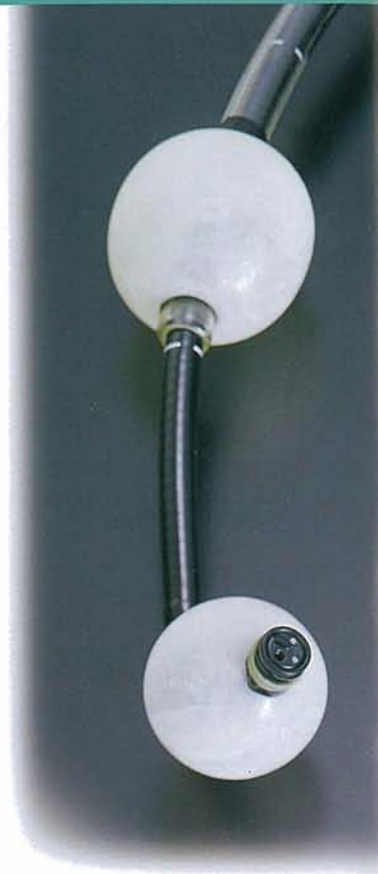
The small intestine has long been the most difficult organ to access in gastrointestinal endoscopy, therefore it has been known as "The Dark Continent." Now, with the introduction of Fujinon's new Double Balloon Endoscopy System, endoscopists are able to shed light on this uncharted territory while providing much needed therapeutic treatment.

Driven from new engineering innovations in flexible endoscopy, Fujinon makes total therapeutic enteroscopy a reality.

Anterograde route

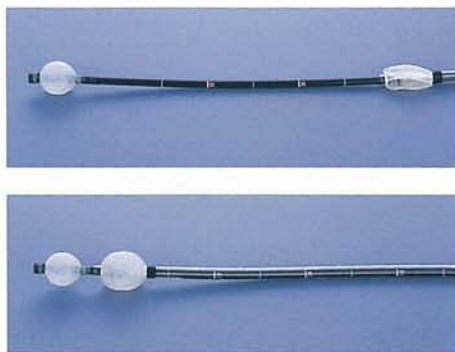


Retrograde route



Newly Developed Overtubes and Balloons

The new, exclusively developed specialized balloons and overtubes ensure complete positioning of the endoscope in the small intestine. In addition, the tip of the scope can be smoothly inserted to reach the area of diagnosis without risk of injury.



Newly Developed Balloon-Pump Control (PB-20)

The all new PB-20 Balloon Pump Controller has been totally redesigned to simplify operation. Now, balloons can be easily controlled via hand remote control or foot switch - whichever is more convenient for the physician. In addition, the PB-20 allows the current status of each balloon to be displayed directly on the hand remote control. This enhancement ensures much smoother endoscopic examination and improves overall procedure efficiency.



EN-450P5



EN-450T5

endoscopic approach



Clinical pictures in small intestine



Ileal adenoma



Acute hemorrhagic necrotizing enteritis



Ileal ascariasis



Ileal vascular ectasia

EN-450P5 (Enteroscope Standard Type)

The innovative EN-450P5 is the world's first video enteroscope that allows the observation of the entire small intestine with two balloons fitted onto the tips of the scope and over tube. The EN-450P5 has a 2.2mm forceps channel that enable routine biopsy as well as other common therapeutic interventions. Furthermore, the unique Double Balloon method allows for visualization of any region of the small intestine. The slim 8.5mm outer diameter of the P5 allows for especially smooth insertion via the antegrade route.

EN-450T5 (Enteroscope Treatment Type)

Treatment capacity has been greatly expanded with the EN-450T5, which is equipped with a 2.8 mm forceps channel that allows the use of almost all general therapeutic accessories and variety of accessories such as APC Probe, Clip, Diathermic Coagulator, and other therapeutic interventions.

EC-450BI5 (Double Balloon Colonoscope)

Through the use of the unique Double Balloon method this new colonoscope facilitates easier access in cases of difficult colonoscopies. Utilizing a small diameter and reduced bending radius, the new Double Balloon Colonoscope also allows for a flexible approach to lesions requiring EMR.

Double-Balloon Endoscopy Method

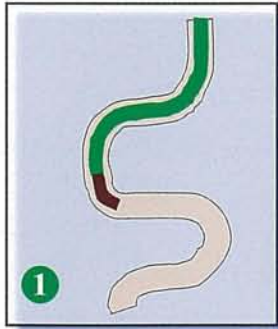
The methods that are currently available for endoscopic insertion into the small intestine are push endoscopy, the Sonde method, and the ropeway method. All are far from ideal. Now, Fujinon has developed a new Double Balloon method jointly with Jichi Medical School, Japan, which is capable of detailed observation and treatment of the whole small intestine with minimal discomfort to the patient.

The insertion method of this system, which materialized as an idea of Dr. Hironori Yamamoto, MD, Department of Gastroenterology, Jichi Medical School, is truly revolutionary as an endoscopic insertion method. Here is the principle of the system.

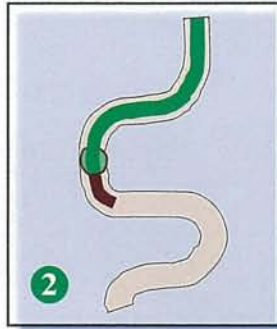
Established Indications for Endoscopy

- Unexplained digestive bleeding
- Crohn's disease
- Radiographic abnormalities of the small intestine
- Unexplained chronic diarrhea and chronic abdominal pains
- Multi-generating polyps

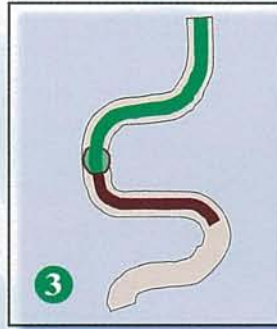
The Principle



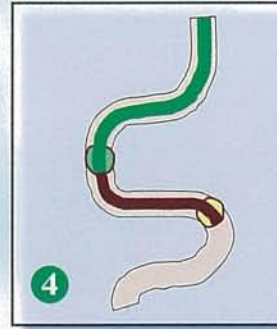
1 Insert an endoscope through an overtube.



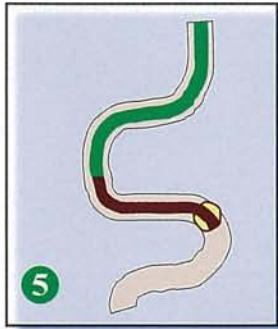
2 In order to grip the small intestine, inflate the balloon on overtube.



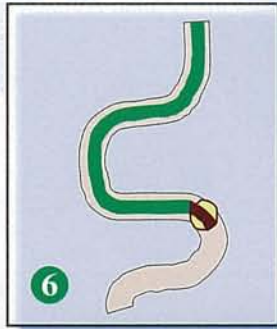
3 The scope is inserted further over the overtube.



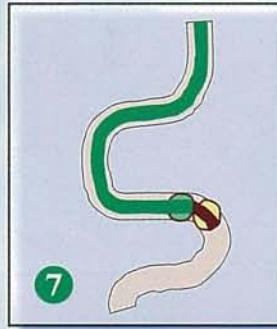
4 Then the balloon on the endoscope is inflated to grip the small intestine.



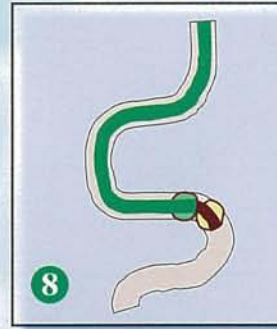
5 Deflate the balloon on overtube.



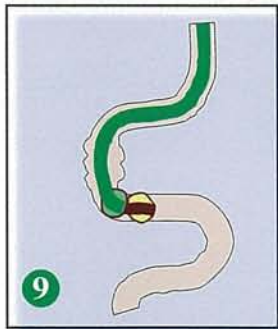
6 The overtube is advanced along the endoscope.



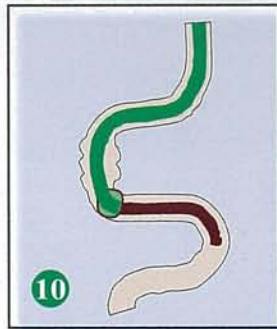
7 Then the balloon on the overtube is inflated to grip the small intestine.



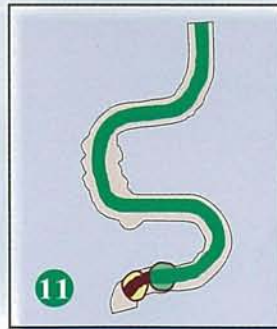
8 Confirm the small intestine is surely gripped with two balloons.



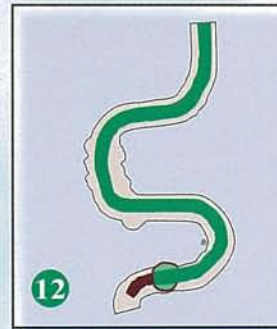
9 With two balloons inflated on scope and over tube, the endoscope is gently withdrawn together with the overtube to get it straight.



10 Again insert the endoscope.



11 These procedures are repeated to get these balloons fixed in deeper and deeper locations.



12 With a set of the above procedures repeated, the scope is advanced steadily up to the depths of the small intestine.

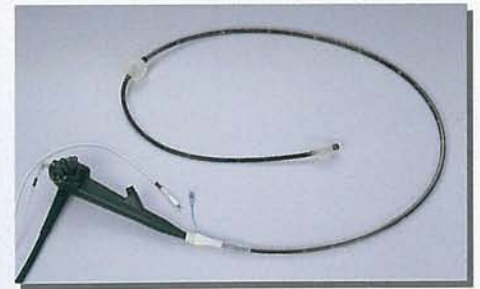
Operating Instructions

This product should only be used by physicians who have sufficient understanding of the clinical procedure and have undertaken sufficient research at research facilities or training facilities for this product to be proficient in the clinical procedure.

*This product was manufactured by FUJINON under the guidance of Dr.H.Yamamoto, the Department of Gastroenterology, Jichi Medical School, Japan.

Double Balloon Endoscope Specifications

	EN-450P5	EN-450T5	EN-450T5/W	EC-450B15
Viewing direction	Forward	Forward	Forward	Forward
Observation range	5~100mm	4~100mm	3~100mm	3~100mm
Field of view	120°		140°	
Distal end diameter	8.5mm		9.4mm	
Flexible portion diameter	8.5mm		9.3mm	
Bending capability : UP / DOWN		180°		
LEFT / RIGHT		160°		
Forceps channel diameter	2.2mm		2.8mm	
Working length		2,000mm		1,520mm
Total length		2,300mm		1,820mm
Image area & Forceps entry position				



Overtube Specifications



	TS-12140	TS-13140	TS-13100
Outer diameter	12.2mm	13.2mm	13.2mm
Inner diameter	10mm	10.8mm	10.8mm
Distal end diameter	8.7mm	9.8mm	9.5mm
Outer diameter(Balloon)	40mm	40mm	40mm
Working length	1,350mm	1,350mm	950mm
Total length	1,450mm	1,450mm	1,050mm

BS-2 Balloons



PB-20 Balloon Pump Controller / Remote Control Specifications



Power supply	120V/60Hz/0.8A	230V/50Hz/0.5A
Power consumption(rated)	0.58A	0.37A
Set pressure accuracy	±2kpa	
Set pressure of balloon	5.6kpa	
Maximum flow rate of pump	170ml±50ml/10sec.	
Dimensions	350(W) X 130(H) X 420(D)mm	
Weight	10kg(Main unit), 0.4kg(Remote switch)	

Processor EPX-4400

Processor VP-4400 Specification

Power	120V 60Hz 0.36A / 230V 50Hz 0.2A
Type of color	NTSC(Progressive) / PAL(Progressive)
Current consumption (rated)	0.31A / 0.17A
Image pickup method	Simultaneous
Image pickup device	Color chip CCD
S/N	More or 40dB
Metering mode	AVE / PEAK
Gain	Normal, +2dB, +4dB, +6dB
Freeze mode	Field / Frame
Image zoom	Electronic Zoom x1 - x2 (0.05 step)
Memory	Patient data: 44 patients / Clinical procedure: 20 types Dr. Name: 20 doctors / Dr. Page: 5 patterns
Digital Outputs	DVI (Digital Visual Interface) : LCD monitor DV (Digital Video) : Digital Recorder USB (Universal Serial Bus) : Output for digital printer Ether-Net : Network output for PC connection CF (Compact Flash) : Output of still image to memory card
Applicable Endoscopes	FUJINON EVE 400 system
Dimensions (W x H x D)	350 x 75 x 420mm
Weight	8.0kg



Light Source XL-4400 Specification

Power	120V 60Hz 4.1A / 230V 50Hz 2.1A
Current consumption (rated)	3.7A / 1.9A
Lamp rated value	Main lamp : 15V300W short-arc Xenon lamp Emergency lamp : 12V75W Halogen lamp (SD lamp)
Light control	Automatic light control by CCD image output on CCD (also, available for Operation Manual)
Lamp cooling method	Forced air cooling
Air supply pump	Normal / Low / OFF
Applicable Endoscopes	FUJINON EVE 400 system
Dimensions (W x H x D)	350 x 130 x 420mm
Weight	16.0kg