

MW39

Endoscopy Training System

Instruction Manual



■ Introduction

Before use / Features P.1-P.2
Safety Precautions P.3

■ Before You Start

Package Contents P.4

(Straight Colon Model)

■ Preparation P.5
■ Training P.6
■ Colon Removal P.7-P.8

(Anatomic Colon Model)

■ Preparation P.9-P.11
■ Training P.12
■ Colon Removal P.13
■ Cleaning P.14
■ Skills P.15-P.16



■ Before Use

We thank you very much for your purchase of this Endoscopy Training System.

This system has been specifically designed to improve endoscopic performance as measured by national assessment programs such as the Fundamentals of Endoscopic Surgery™ (FES), Global Assessment of Gastrointestinal Endoscopic Skills (GAGES) and Assessment of Competency in Endoscopy (ACE).

■ Appropriate Use

This system has been developed for the training of medical professionals only. Any other use, or any use not in accordance with the enclosed instructions, is strictly prohibited. Kyoto Kagaku Co.,Ltd. cannot be held responsible for any accident or damage resulting from such use.

Please use this model carefully and refrain from subjecting it to any unnecessary stress or wear.

■ Features

This system consists of a straight colon model and an anatomic colon model which allows the learner to gain the following key endoscopic skills through deliberate practice:

1. Fundamental scope navigation skills using dials and torque
2. Basic tool skills
3. Working in retroflexion
4. Preventing, managing and reducing loops
5. Thorough mucosal inspection

■ Target Skills

- | | |
|-------------------------|-------------------------|
| 1. Straight colon model | 2. Anatomic colon model |
| 1) Scope Manipulation | 1) Loop Management |
| 2) Tool Targeting | 2) Mucosal Inspection |
| 3) Retroflexion | |

The American Board of Surgery Flexible Endoscopy Requirements

In March 2014, the ABS announced a new requirement to ensure all ABS-certified general surgeons have completed a standard curriculum in the use of endoscopic techniques. This new requirement will apply to certification applicants who complete their residency training in the 2017-2018 academic year or thereafter.

During their general surgery residency, applicants will be required to have completed the ABS Flexible Endoscopy Curriculum, which provides a stepwise instructional program for residents to acquire the essential knowledge and skills to perform flexible endoscopy.

In addition, one of the final steps in the curriculum is successful completion of the Fundamentals of Endoscopic Surgery™ (FES) program offered by SAGES.

The Endoscopic Training System (ETS) has been designed to allow practitioners at all levels the opportunity for deliberate practice, to achieve proficiency in flexible endoscopy skills.

Source: The American Board of Surgery Website

Supporting Literature

Trinca K, Cox T, Pearl JP, Ritter EM Validity Evidence for the Simulated Colonoscopy Objective Performance Evaluation (SCOPE) Scoring System. American Journal of Surgery 2014 FEB 207(2);218-25.

Ritter EM, Cox T, Trinca K, Pearl JP Simulated Colonoscopy Objective Performance Evaluation (SCOPE): a non-computer-based tool for assessment of endoscopic skills. Surgical Endoscopy 2013 27:4073-4080.

Franklin BR, Placek SB, Gardner AK, Korndorffer JR, Wagner MD, Pearl JP, Ritter EM, Preparing for the American Board of Surgery Flexible Endoscopy Curriculum: Development of Multi-institutional Proficiency-Based Training Standards and Pilot Testing of a Simulation Based Mastery Learning Curriculum for the Endoscopy Training System. Presented at the Association for Surgical Education annual meeting, San Diego, CA April 2017 (undergoing peer review)

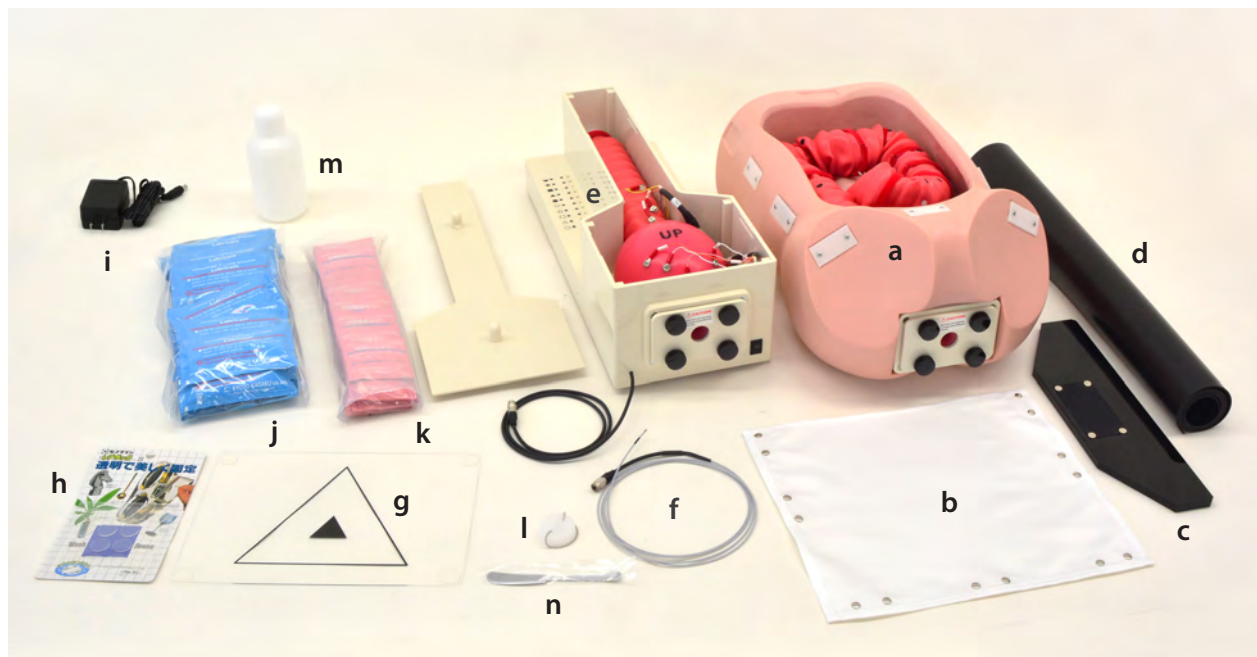
Ritter EM, Taylor ZA, Wolf KR, Franklin BR, Placek SB, Korndorffer JR, Gardner AK. Simulation Based Mastery Learning for Endoscopy Using the Endoscopy Training System: A Strategy to Improve Endoscopic Skills and Prepare for the Fundamentals of Endoscopic Surgery (FES) Manual Skills Exam. Presented at the Society of American Gastrointestinal and Endoscopic Surgeons annual meeting, Houston TX, March 2017 (undergoing peer review)

The safety rules below focus on the safety of the user; please read carefully before using the product.

⚠ WARNING	
If the model or the control box becomes hot or begins to smoke, immediately unplug the power cord.  This is a major fire hazard.	Unplug the power cord when the model is not in use.  This will prevent electrocution or fire hazard that may cause burn or damage to the model.
Remove any dust that has accumulated on the power plug and insert the plug completely into the power socket.  Dust and incomplete connection can lead to a major fire hazard.	Keep the model, its machinery and power cord away from water or detergent.  This can lead to fire hazard or electrocution.
Do not handle the power cord with wet hands.  This is to avoid electrocution.	Keep flammable materials away from the model.  This could damage the product or cause a fire hazard.
Use the designated power supply.  Misuse may lead to damage and fire hazard.	When unplugging the power cord, do it by holding the plug itself and pull it.  Unplugging by the cord may lead to damage to the cord itself, fire hazard or electrocution.
Do not attempt to take apart or modify the model.  This could lead to fire hazard, electrocution and injury.	Do not bend, twist or damage the power cord.  This is to avoid to fire hazard and electrocution.

⚠ CAUTION	
Handle the model and its components with care. Do not apply excessive force or pressure.	Do not mark the model with a pen or leave printed materials in direct contact with the model's surface. Inks marks on the model are not removable.
The model may be cleaned with a wet cloth, if necessary, using mild soapy water or diluted detergent.	Never use organic solvent like paint thinner or alcohol to clean the skin, as this will damage the model.
Store the model at room temperature, away from heat, direct sunlight and moisture to prevent discoloration or other damage.	Discoloration of the surface may occur over time. However, discoloration does not affect the function of the model.

Your model should include the following components:



○ Anatomic colon model

- a. Installed in the body:
 - 1) Colon-rectum tube.
 - 2) Anus plate.
 - 3) Colon tube fixtures.
 - Fixture type A (3 rings with spring).
 - Fixture type B (7 rings without spring).
 - 4) Colon layout guide.
- b. Abdomen cover.
- c. Stand.
- d. Anti-slip mat.

○ Straight colon model

- e. Installed in the model:
 - 1) Straight colon tube.
- f. Simulated biopsy tool.
- g. Scope manipulation screen overlay.
- h. Extra glue patch.
- i. AC adapter.

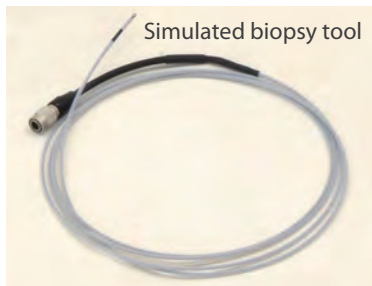
○ Supplies

- j. Concentrated lubricant:
 - 1) 30 BLUE packets (50 ml each).
- k. Endoscope lubricant:
 - 1) 30 PINK packets (20 ml each).
- l. Colon end cap with chain.
- m. Plastic bottle.
- n. Spatula.

Preparation

(Straight Colon Model)

① Connect the power adapter and attach the scope manipulation screen overlay.



1. Connect the cable of the simulated biopsy tool to the cable from the colon model. Insert this simulated biopsy tool into the port of the Endoscope. The black stripe on the tip INDICATES the correct distance (half an inch) for the retroflexion task.



2. Insert the AC adapter connector into the power port on the left side of the unit.



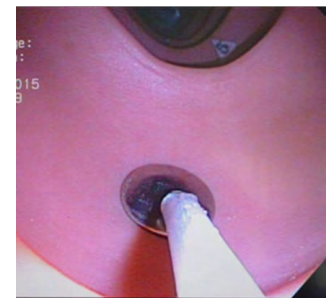
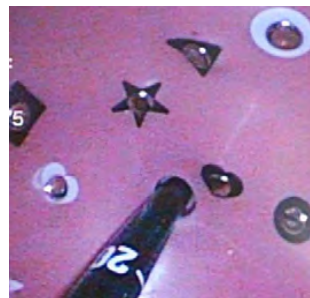
3. Clean the monitor screen, and peel the thin film off of the glue patches on the corner of the overlay. Fit the scope manipulation overlay onto the monitor. If the glue patches don't work well, clean them with water to restore adhesion.



4. Turn on the power switch on the bottom right side and start training.

① Training with the straight colon model

1. Apply a small amount Endoscope lubricant gel (PINK packet) to the Endoscope tip, and insert it into the anus to begin training. *See p.14 for task description and training curriculum.*
2. When holding the simulated biopsy tool on the target for 5 seconds, an audible tone will sound and corresponding light will illuminate. If target contact is interrupted before 5 seconds has passed, the light will not illuminate.



* There are 10 target discs in the straight colon that correspond to 10 orange lights on the model. There are also 10 discs (black and white shapes - heart, star, square, triangle, circle) that correspond to 10 green lights on the model. Holding the simulated biopsy tool in place on each disc for 5 uninterrupted seconds will illuminate the light showing achievement status.

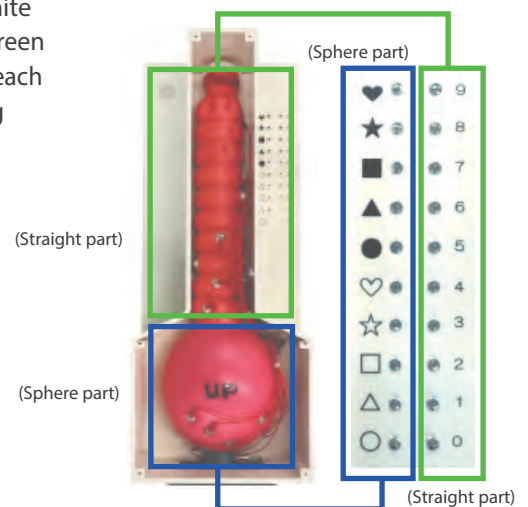
Targets and Shapes

Skills/Location	LED	○	△	□	☆	♡	●	▲	■	★	♥
Retroflexion (Sphere part)	Green	0	1	2	3	4	5	6	7	8	9
Tool targeting (Straight part)	Orange	0	1	2	3	4	5	6	7	8	9

4 sound effects for actions

Sound effect	When it happens	Meaning
1) Beep ending high frequency	Correct target contact	One tone for each second of contact
2) Beep ending low frequency	Target contact lost	Failure
3) Beep with counting rhythm	During target contact	One tone for each second of contact
4) Beep with two peaks	After maintaining contact for 5 secs	Success

3. To reset the light panel, turn off the model and restart.



Colon Removal

(Straight Colon Model)

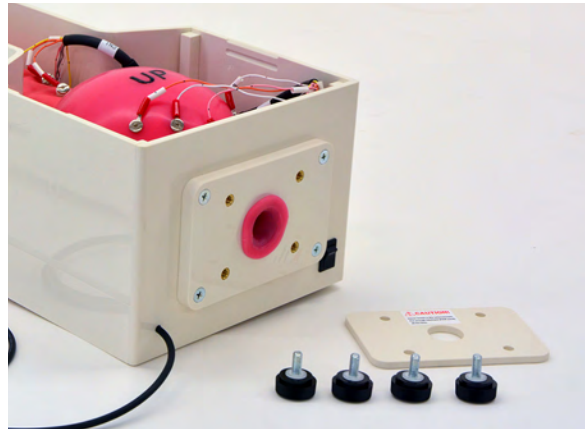
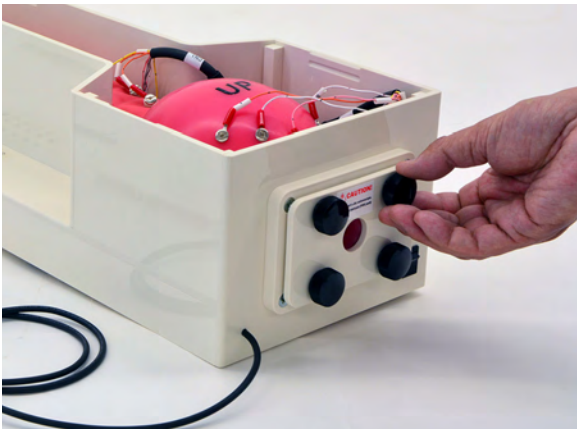
NOTE: It is not recommended that you clean the straight colon model on a regular basis. If needed, add WARM water to the tube (avoid hot water) and shake. Place chained cap on the tube and hang to dry. We recommend drying for at least 24 hours to avoid mold build up.

① Detach the straight colon tube

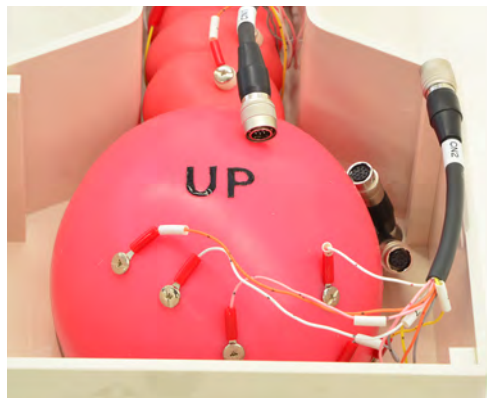


1. Remove the top plate using the two knobs.

2. Untighten four screws (counterclockwise) to detach the anus plate which holds the straight colon tube.



3. Detach the two cable connectors (CN1 and CN2) between the colon tube and the electric contacts in the body. Pull the connectors in opposite directions to separate them.



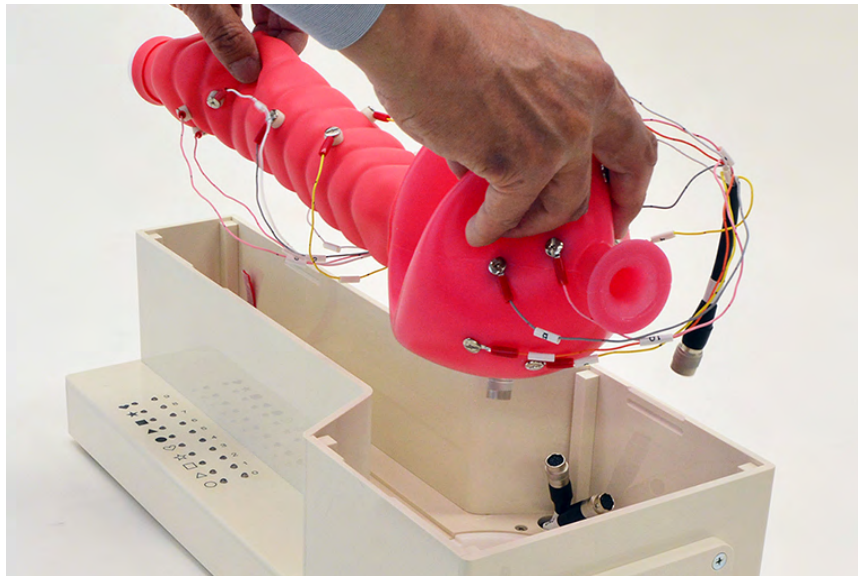
Colon Removal

(Straight Colon Model)

4. Remove the Velcro tape holding the tip of straight colon tube, and pull the anus parts from the anus plate to detach.



5. Detach the straight colon tube.



Preparation

(Anatomic Colon Model)

① Pour the lubricant into the colon-rectum tube

1. Pour 1 BLUE packet of lubrication slowly into the colon tube.



2. Replace the tube cap tightly. Work the lubricant through the colon tube.



Please note: Leakage may result if too much lubricant is added at once; use enough for each training session and add more if needed.

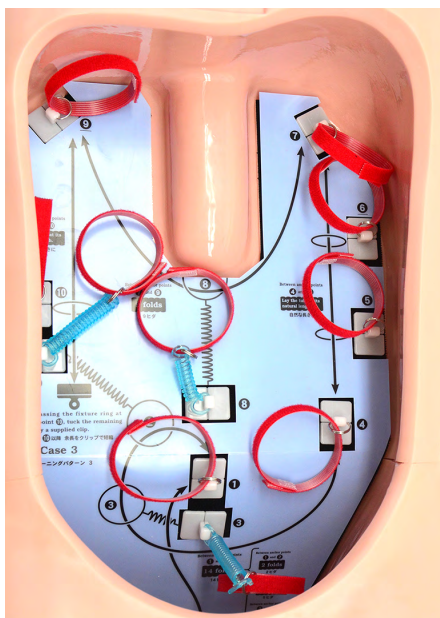
Preparation

(Anatomic Colon Model)

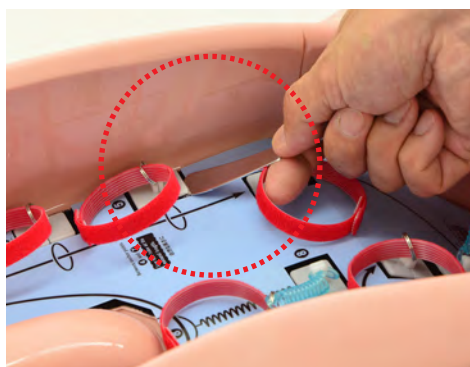
② Install the colon-rectum tube in the anatomic model



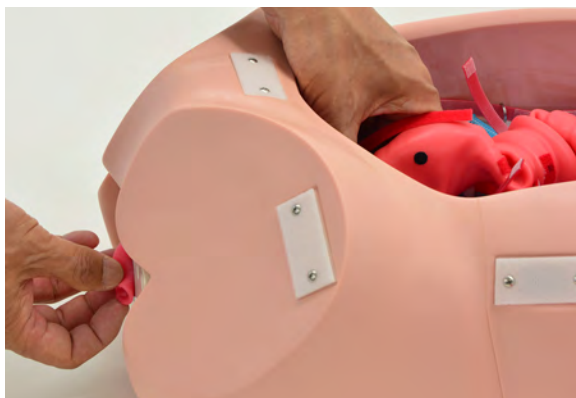
1. The black dots on the colon-rectum tube indicate the upper side. The numbers 1-10 on the side of the colon-rectum tube correspond to numbers on the fixture base and indicate where the Velcro tapes should be attached.



*If the fixture base needs to be removed, use the spatula.



2. Insert the anal end of the colon-rectum tube through the opening of the anatomic body wall (do not use any instrument to grasp the colon-rectum insert, as this may cause damage). Cover with the anus plate, and fix the plate in place using the four screws.

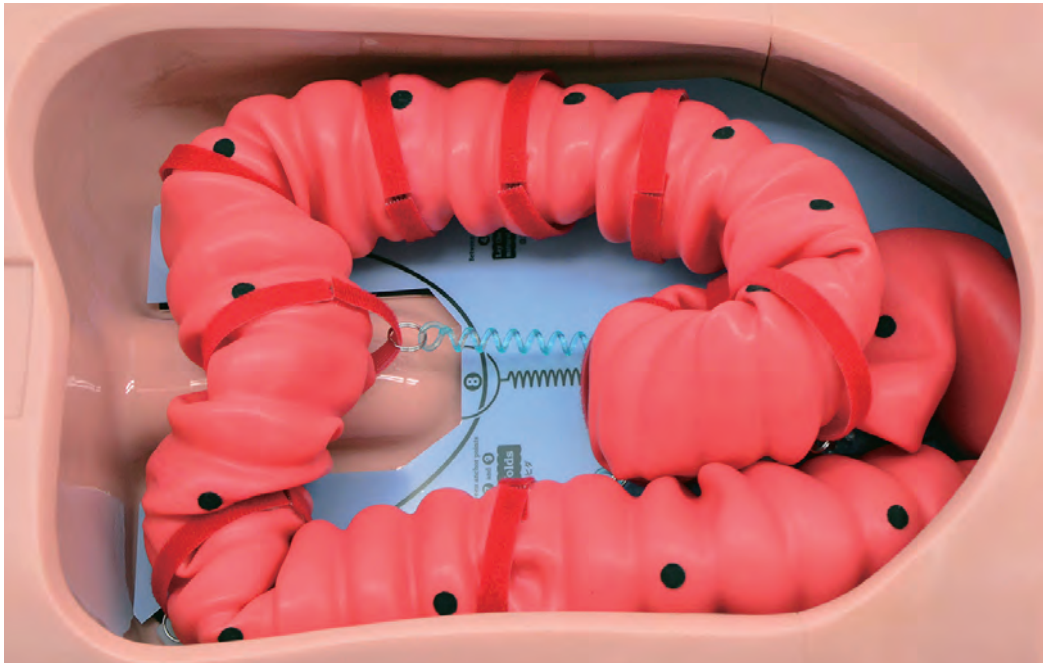


Preparation

(Anatomic Colon Model)



3. Install the colon-rectum tube by attaching the Velcro tapes, matching the numbers on the side of the tube to the numbers on the fixture base.
4. For correct colon installation, all black dots on the colon-rectum tube should be facing upward.

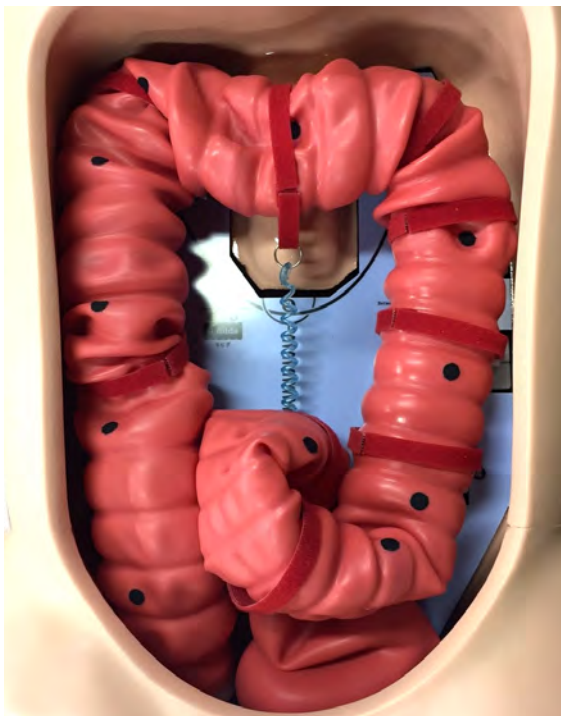


5. Attach the abdomen cover with the Velcro fasteners and set the model on a level table on top of the anti-slip mat.
6. The abdomen cover does not completely cover the opening. (The space at the top is intended to allow for confirmation of the endoscope's location within the loop reduction zone. *See Loop Management, p.15.*)

① Training

1. Before insertion of the Endoscope, check to confirm there is enough lubricant in the anus. If a bit dry, add more lubricant with your finger.
2. Insert the tip of the Endoscope into the anus opening.

Caution : Put some endoscope lubricant (PINK packet) on the Endoscope if the insertion does not go smoothly. Do not continue training with poor lubrication as it may damage the colon-rectum tube.



3. The lines on the inside of the colon-rectum indicate the proper area to practice the loop reduction. The green line (under No. 7 Velcro) shows the beginning, and the black line (under No. 9 Velcro) shows the end of the loop reduction zone.

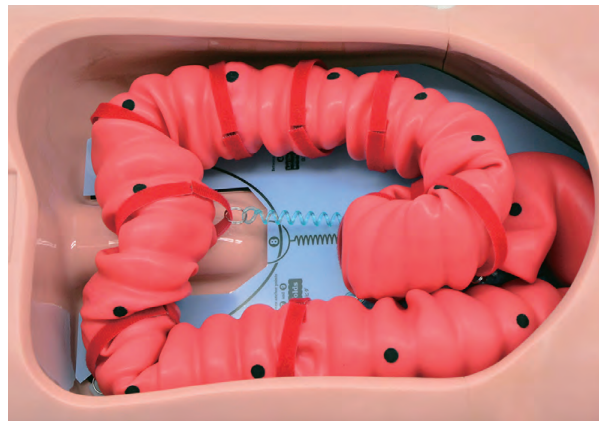
4. Change the body position if needed. Attach the stand on the anatomic body to stabilize lateral position.
5. In the colon-rectum tube there are 10 simulated polyps for the mucosal inspection task.



Colon Removal

(Anatomic Colon Model)

① Detach colon-rectum tube



1. Detach the anus plate.

Untighten four screws (counterclockwise) to detach the anus plate which holds the colon-rectum tube.



2. Detach each of the Velcro tapes holding the colon-rectum tube in place. Then remove the anus from the anus plate to detach. Lift the colon-rectum insert from the body model.



Caution : Do not pull hard on the tube. Excessive force on the tube may cause damage.

Cleaning

(Anatomic Colon Model)

① Cleaning the colon-rectum tube

1. Remove the colon end cap by turning it counterclockwise.



2. Pure water into the colon-rectum tube. Warm water is recommended for efficient cleaning. Do not use hot water.

3. Shake colon tube to dissolve the left over lubricant, and drain.

4. Repeat this process until no lubricant is left in the colon-rectum tube.



5. Attach the colon end cap with chain to colon tube, and hang it to dry. We recommend allowing 24 hours to dry completely.

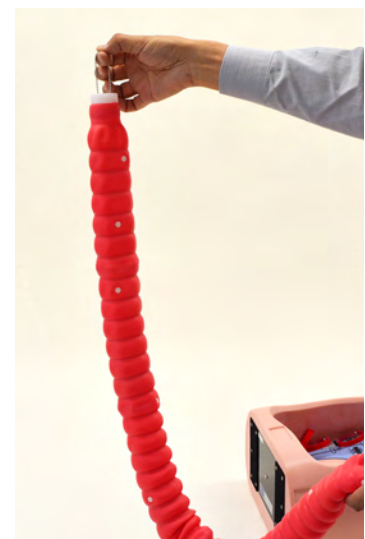
6. When the colon tube is dry, refit the original colon cap (without chain) on the anatomic colon body.



***We strongly recommend the colon-rectum tube is dried completely to protect it from mold build-up during storage.**

If mold is found in the colon-rectum tube, use a citric acid based mold killer or remover that is bleach-free and phosphate-free. We strongly recommend you test it on an inconspicuous area before use, as mold killer/remover sometimes erases markings or causes color to fade.

8. Clean the colon-rectum tube and the colonoscope immediately after use.



Skills for the straight colon model

Scope Manipulation

Performing basic endoscopic navigation, using tip deflection & torque of the scope.

Task: Shape alignment

- Align the numbered white triangles within the colonic lumen. The small black triangle should be within the numbered triangle and both triangles should be within the large black triangle as shown.
- 10 shapes to be aligned, in order (#0-#9) and accomplished sequentially.

Mastery Training Goal: 10/10 shapes in 121 seconds or less 2 consecutive times.
Overtraining : 5 additional times (does not have to be consecutive.)



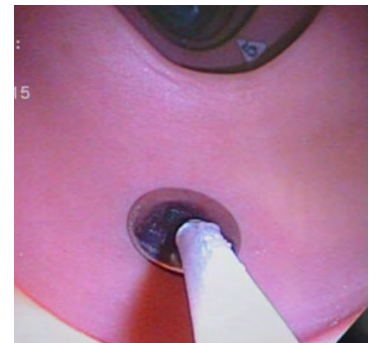
Tool Targeting

Hand-eye coordination with biopsy forceps and an endoscope.

Task: Find 10 targets, illuminating all orange lights on the model.

- Connect the simulated biopsy tool to the metal disc within the colonic lumen. Deploy and retract the simulated biopsy tool as needed during task.
- Identify each metal disc that corresponds to the numbered triangles. Deploy the simulated biopsy tool and hold in place for 5 seconds, listening for double tone and watching for corresponding orange light to illuminate on straight model base.
- A downward tone indicates disruption to the connection, indicating the need to reconnect the simulated biopsy tool for an additional 5 seconds until double tone is heard and light is illuminated.
- Starting at the "Stop" cap located at the end of the model, target all 10 disks sequentially while withdrawing.

Mastery Training Goal: 10/10 targets in 243 seconds or less 2 consecutive times.
Overtraining : 5 additional times (does not have to be consecutive.)



Retroflexion

Bending the endoscope backward to identify and navigate to targets. Simulates evaluation of cardia of stomach and distal rectum.

Task: Find 5 white targets, illuminating 5 green lights on the model.

- The simulated biopsy tool should be introduced until the black indicator line is seen. The tool is not to be manipulated during the task.
- Hold simulated biopsy tool on each target for 5 seconds until a double tone is heard and the corresponding light on the straight colon base is illuminated.
- A downward tone indicates disruption to the connection. The biopsy tool must be held in place for an additional 5 seconds until double tone is heard and corresponding light is illuminated.
- 5 white discs to be completed by shape and color.
(Black shapes can be used for additional practice, but only the white shapes were used in developing the mastery training curriculum.)

Mastery Training Goal: 5/5 white shapes in 159 seconds or less 2 consecutive times.
Overtraining : 5 additional times meeting the mastery training goal (does not have to be consecutive.)



Skills for the anatomic colon model

Loop Management

Scope navigation to manage the correct reduction of a standard alpha loop.

Task: Correct identification and management of a standard alpha loop.

- Insert endoscope into the colon-rectum tube and begin advancing the scope.
- Loss of 1:1 and recognition of loop formation should occur in the zone between the green and black mucosal lines. At this time, the scope should be visible in the transverse colon above the abdominal cover.
- When a loop is formed it needs to be recognized and then successfully reduced to continue advancing the endoscope. Use of suction will assist with proper loop reduction.

Mastery Training Goal: Loop reduction and navigation to cecum (stop) in 261 seconds or less 2 consecutive times.



Mucosal Inspection

Task: Identification of simulated polyps

- Perform a full mucosal inspection to identify polyps within the colonic mucosa during withdrawal of the scope from the cecum to the anus.
- True polyps are well-circumscribed (as shown in the picture), differentiating them from mucosal folds.

Mastery Training Goal: >6 polyps identified in 180-480 seconds 2 consecutive times.



For more information on the ETS curriculum, please see:

E. Matthew Ritter MD, Zachary A. Taylor DO, Kathryn R. Wolf MD, Brenton R. Franklin MD, Sarah B. Placek MD, James R. Korndorfer Jr. MD MHPE, Aimee K. Gardner PhD. (Submitted for publication March, 2017). Simulation Based Mastery Learning for Endoscopy Using the Endoscopy Training System: A Strategy to Improve Endoscopic Skills and Prepare for the Fundamentals of Endoscopic Surgery (FES) Manual Skills Exam.



Caution

Do not let ink from pens, newspapers, product manual or other sources contact the model. Ink marks on the model will be irremovable.

• For inquiries and service, please contact Limbs & Things Inc. or KYOTO KAGAKU CO., LTD.

■ Parts list

Item code	Part name	
11419-010	Straight colon tube	1
11419-020	Colon-rectum tube	1
11419-030	Colon tube fixtures (7 rings without spring, 3 rings with spring)	1
11361-040	Lubricant for colon-rectum tube (Blue packs) 30bags	1
11361-050	Endoscope lubricant (Pink packs) 30bags	1
11419-040	Simulated biopsy tool	1



Colon tube fixtures



Straight colon tube



Lubricant for colon rectum tube



Colon-rectum tube



Endoscope lubricant



Simulated biopsy tool

■ Distributor



12127 Apache Avenue Savannah, GA 31419, USA
Toll-Free 1866-465-4627; 001 912 629 0357
customerservice@limbsandthings.com

■ Manufacturer

 **KYOTO KAGAKU co.,LTD**

WEB • www.kyotogagaku.com

E-MAIL • rw-kyoto@kyotokagaku.co.jp

15 kitanechoya-cho Fushimi-ku Kyoto 612-8388, Japan
TEL: +81-75-605-2510
FAX: +81-75-605-2519

■ US Company of Manufacturer



WEB • www.kkamerica-inc.com

E-MAIL • info@kkamerica-inc.com

3109 Lomita Boulevard, Torrance, CA 90505-5108, USA
TEL: +1-310-325-8860
(Toll-free in North America: 877-648-8195)
FAX: +1-310-325-8867