Given Imaging Announces FDA Clearance of Capsule Endoscopy for Pediatric Use

The FDA has cleared capsule endoscopy for pediatric use in children ages 10–18.

FDA clearance was based on a 30-patient study conducted by Ernest G. Seidman, M.D., Chief, Division of Gastroenterology, at Sainte-Justine Hospital in Montreal. The study was a comparative, prospective self-controlled trial of pediatric patients suspected of having Crohn's disease, intestinal polyposis, or occult or obscure GI bleeding.

The study concluded that capsule endoscopy diagnosed or definitively excluded a bleeding source, small bowel polyps or Crohn's disease in twenty-nine of thirty patients studied. The capsule was well tolerated in all patients with no adverse symptoms.

"Clearance of the Given System for pediatric use means that Gastroenterologists will now be able to utilize capsule endoscopy for non-invasive visualization of the small intestine in this patient segment. That will provide a higher diagnostic yield while eliminating unnecessary sedation, radiation, risks and trauma associated with invasive procedures, including scoping and exploratory surgery," said Gavriel D. Meron, President and CEO of Given Imaging.

"Capsule endoscopy is a safe, effective and compassionate method for diagnosing small bowel disorders in children. We have seen many cases of patients who suffered from undetected small bowel disorders and, after ingesting the capsule, received a definitive diagnosis and subsequent treatment which significantly improved their lives," said William R. Treem, MD, Chief of Pediatric Gastroenterology and Nutrition, Duke University. "In one case, a young girl suffered for months with severe abdominal pain and bleeding, and underwent numerous invasive tests with no diagnosis. She subsequently ingested the M2A capsule and was diagnosed with Crohn's disease. Today, her condition is under control and she is living the normal life of a teenager. I believe that capsule endoscopy should be a first line diagnostic tool for children with suspected small bowel disorders." ■

Textbook of Gastroenterology, Fourth Edition

Yamada T, Alpers DH, Kaplowitz N et al, eds
Lippincott, Williams and Wilkins, 2003
ISBN: 0-7817-2861-4; $279.00

The above two-volume textbook has been reviewed. The multi-author book is clearly well written with excellent diagrams and color plate areas in each volume with pertinent arrows in volume two and arrows in black and white diagrams in the remainder of the text. It is well referenced with encyclopedic, mostly up-to-date material.

One criticism is its weight of 25 pounds for the two volumes. I would recommend a 3 volume set to decrease its weight per volume. The chapter on the approach to patients with nutritional problems was not significantly updated from the Third Edition and is lacking such newer endoscopic techniques as jejunal tube placement. I recommend that the editors use an author with extensive nutritional support experience for the above chapter in the next edition.

In summary, I believe this book is a necessary asset for medical libraries catering to students and housestaff, each training unit for GI Fellowship, and clinicians who practice gastroenterology.

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Living with Hemochromatosis

Everson GT and Weinberg H.
Hatherleigh Press, 2003
ISBN: 1-57826-104-X; $15.95

I am 76 years old, a retired Air Force fighter pilot and an ex Korean POW. I relate these facts not because one gets hereditary hemochromatosis (HH) in prison camp, but one does get a host of other medical possibilities that tend to obscure diagnosis of the more common problems. Being able to report for duty as "medically fit for flying" is a full time occupation of every fighter pilot and I attribute that background to my highly focused attention to medical imperatives i.e. keeping medically fit. It was with this background, that sixteen years ago I received the news: "You have Hemochromatosis" from my doctor. Following a series of tests including a liver biopsy he solemnly advised, "You have a very serious condition only if it progresses. From what we now know, frequent phlebotomies can restore and maintain the proper balance of iron in your joints and organs." I took that warning very seriously and was in the lab twice a week for nearly three months and have since followed my oncologist's recommended phlebotomy schedules. I lead a pretty normal and active physical and dietary life. I travel often and carry a: "To Whom It May Concern" letter, for use by laboratory technicians wherever I am, detailing the specifics as to when I need to be phlebotomized. It works perfectly.

To my knowledge, this wonderful book, *Living With Hemochromatosis,* is the first true "Bible" on the subject. It has expanded my understanding far beyond any other readings or discussions. It has focused my attention on a couple of areas that I want to follow up on. Some details about my own care are now clear and I can improve in those areas. Of considerable interest is the "hereditary" issue and the passing on of mutated genes to offspring. I have never heard this discussed in a meaningful way and the subject is highly developed in this book. The book is very readable with technical detail for those so inclined but completely understandable with my non-technical approach.

I was very taken with the anecdotal stories that expanded my understanding of how others are handling their HH situations and how potentially affected persons sometimes relate to the subject. I was particularly interested in the success and non-success experiences that occur within families when an effort is made to educate specific relatives that may be in the HH "inheritance zone." Next to the patient information, the potential for protecting family offspring may be the most important aspect of the book. The application of gene study is clearly presented and its immediate use to eliminate damage from HH to our offspring is highly encouraging. Considering the vast number of mutated gene carriers that exist worldwide this information should be part of general health textbook teaching in our national school system. I think the medical world and those of us with hereditary hemochromatosis owe the authors a huge vote of thanks for giving us such a wonderfully intellectual and easy read on such a vital subject.

Finally, I think this book should be required reading in every medical school because of its medical importance. Of equal importance, it could be a first class primer for teaching doctors how to talk straight, without complications, to each other and to their patients. And for us patients, this book re-emphasizes that the individual is the person most responsible for his own and his family's health. If you or a friend has hemochromatosis—get this book.

JD
Albuquerque, NM

George W. Meyer, M.D., Book Editor, is on the Editorial Board of *Practical Gastroenterology*