

F-Cal Device

(Fecal impact removal device)



Introduction and
Utilization

F-Cal Device

A new innovative device-based solution for Fecal impaction removal

- ... is designed specifically to remove all forms of fecal impaction. This patented device provides an **effective, efficient, and humane solution with reduced patient pain** for the removal of fecal impactions within the scope of care of midlevel providers including nurses, medical technicians, and home healthcare providers.
- ... is FDA certified Class 1 with 510k exemptions.
- ... was invented by Dr. Patrick Munson, MD, 35 years ER Doctor and Dr. Lerrlyn Nelson, PhD, 30 years in Administration
- ... will most certainly create *a new Standard of Care* for fecal impaction.

Global Health Need:

Fecal impaction is reaching epidemic proportions in the US and around the world, not only in elderly and infirmed patients but people of all ages. Prevalence includes:

- Low fiber diets
- Decreased physical activity
- People with Neurological Disorders
- An aging population
- Chronic Opioid drug use
- Disabled individuals
- Post-Surgical Patients

and other factors ensure that incidence rates are high and will continue to grow.

Global Health Need, continued:

Traditional treatments alone (enemas, oral laxatives, suppositories) are often limited in their effectiveness leaving digital treatment as the preferred non-surgical removal procedure. This is notoriously painful to the patient (and uncomfortable for the health care provider) and can require sedation that extends visit times and necessitate admission. Failure to treat impactions quickly and efficiently at the first venue of care increases costs and reduces capacity availability at hospitals, urgent care units, clinics, other public care facilities.

Fecal impaction (in a completely obstructed colon) can result in damage to the rectal wall where bacterial growth can enter into the bloodstream causing sepsis and even death.

Global Health Need, continued:

According to [EB Medicine.net](http://EBMedicine.net): 1,300,00 patients visit the ER for constipation every year. The fact that the epidemiology of fecal impaction is poorly documented, and the data is not available on percentage of ER visits that are for Fecal Impaction, is testament that the problem has been ignored by the medical profession and institutions.

A study from 2011 shows that there have been 42,500 annual hospital ER visits for Fecal Impaction (**in the USA alone**). The associated mean charge of a fecal impaction ER visit was \$3060.47 in 2014 dollars. [Journal of Clinical Gastroenterology 50\(7\):p 572-577, August 2016.](#)

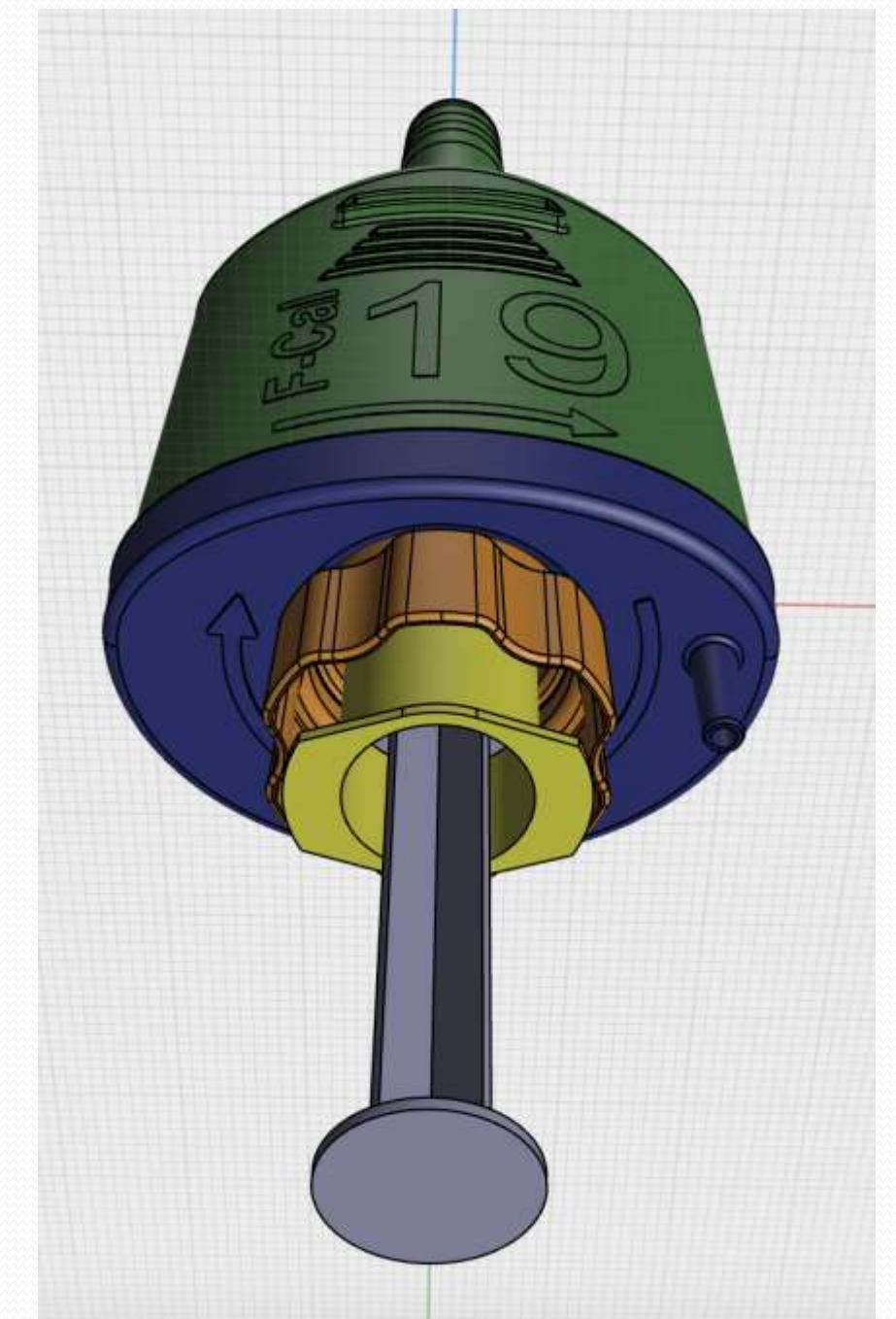
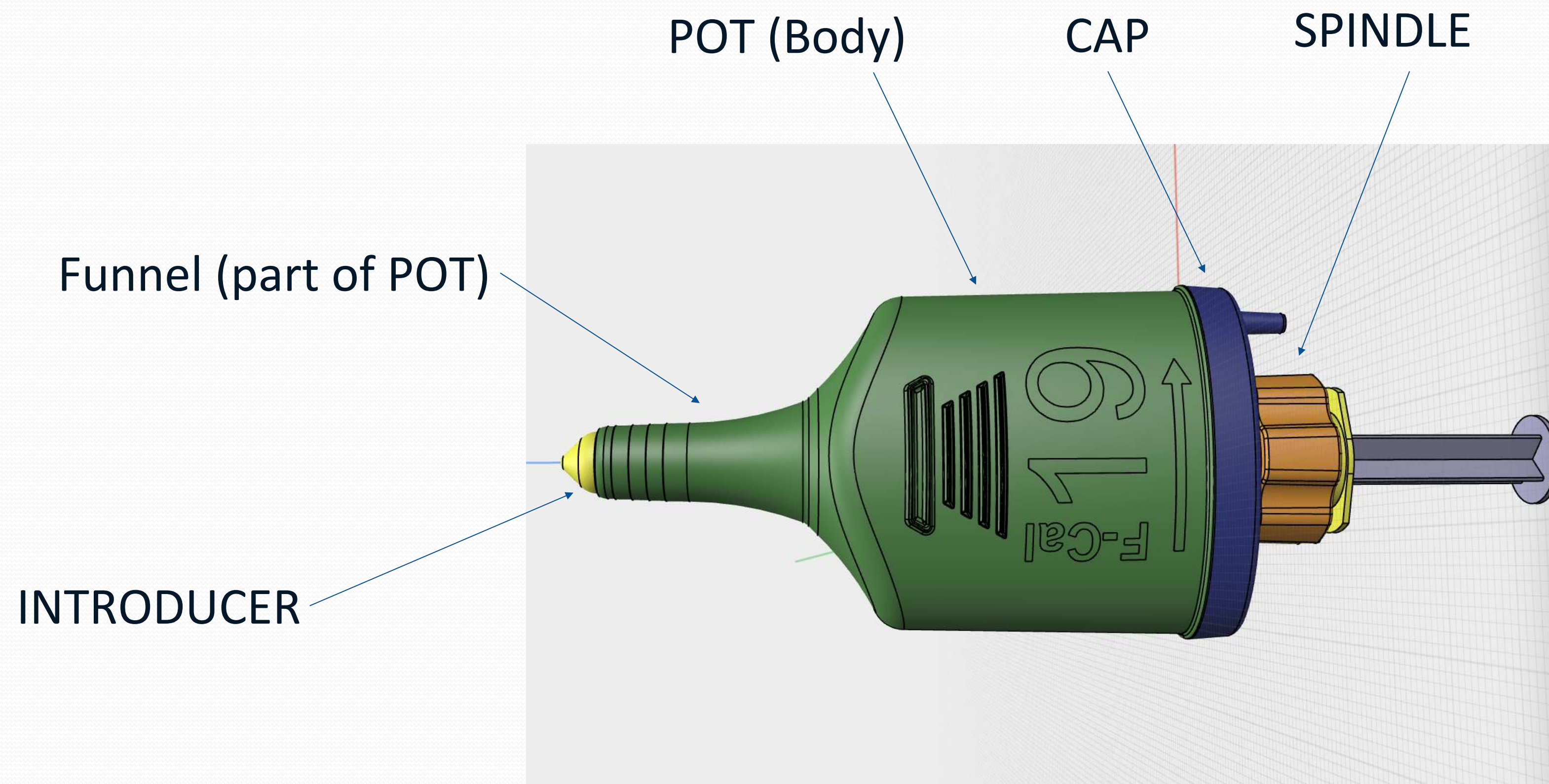
According to a nation-wide study of prevalence and risk factors for fecal impaction in nursing homes, Dr. Enrique Rey et al reported in 2014 that the prevalence of constipation was 70%, and the prevalence of fecal impaction diagnosed with direct rectal exam was 6.6% - this equates to 79,000 fecal impactions annually in nursing homes alone. Many impactions are treated outside of the ER and occur outside of nursing homes, so these numbers for Fecal Impaction capture only a fraction of the total problem. [PLoS ONE Volume 9, Issue 8: e105281, August 2014.](#)

Benefits of the F-Cal Device:

- The implementation of this device will benefit your facility and health care offering by providing a more humane alternative treatment for fecal impaction.
- Dramatically improves quality of treatment, reducing pain and discomfort for the patient, and solving the problem without the fear and excessive pain of digital disimpaction or stimulation with laxatives.
- Saves time and costs in every health care environment from EDs to Urgent care and General practice offices thus freeing-up capacity.
- Simple to use by most levels of care providers.
- The F-Cal kit is complete and ready to use and when in use, isolates the removed stool inside the container.

The F-Cal Device

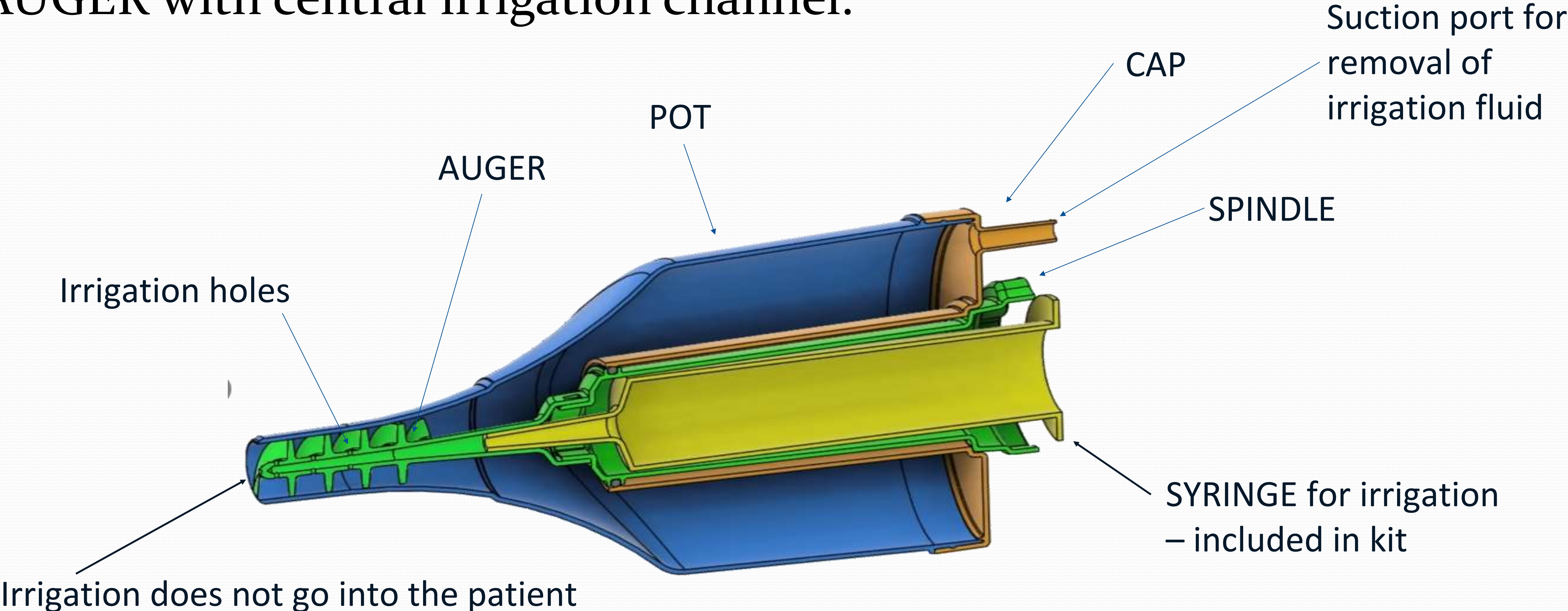
Device with INTRODUCER – As provided in Kit



Do Not Copy or Distribute

The F-Cal Device; cutaway

AUGER with central irrigation channel.



Introduction of F-Cal to your system

- Components are made in the USA using medical grade plastics. All components are cleaned in 99% isopropyl alcohol before packaging.
- The kit is provided with the INTRODUCER as part of the assembly. The AUGER and SYRINGE are loose components in the complete kit.
- Once the F-Cal device has been properly lubricated and introduced into the patient, the INTRODUCER is removed, and the AUGER is inserted in the assembly (it is important to note that the AUGER does not protrude past the end of funnel thereby eliminating the risk of injury inside the body). The F-Cal device can then be used to remove the fecal impaction.

Please reference the simulation video from our website for demonstration:

https://f-cal.com/images/f-cal/F-Cal_video_10-24-2024.mp4

Introduction of F-Cal to your system

- By providing the device to your own clinical providers to use, the value and benefits will become obvious to the users and patients.
- Depending on the prevalence of fecal impaction in your system (ICD 10 Code = K56.41), we will jointly decide the number of devices to be used at the study level. These devices will be provided free of charge with the condition that the study questionnaires are filled out and returned and that the specific providers who used the device share their contact information such that they can be interviewed if needed .
- Following this experience, we are confident that your providers will not want to return to digital dis-impactions or admissions for IV therapy.

Potential Users of the F-Cal Device

- Hospitals – Gastroenterologists, Surgery – Doctors and Nurses
- Emergency Rooms – Nurses and Technicians
- Rehabilitation Centers – Nurses and Technicians
- Clinics – Physicians and Nurses and Technicians
- Home Health Care – Nurses and Technicians
- Long Term Care Facilities – Doctors and Nurses and Technicians
- Elderly Care Facilities – Geriatricians and Nurses and Technicians

Questions raised about the F-Cal device

- Are there potential risks associated with using this device?
 - ❖ Dr Patrick Munson discussed potential complications with physicians, both ED Physicians, Gastroenterologists, and Nurses at two recent medical conferences and hospitals:
 - He consistently received the opinion shared that the complication profile 'should be' very low, if at all, with no actual contraindications.
 - He specifically asked at least a dozen Gastroenterologists at the recent ACG conference about potential injury to patients with the presence of a pedunculated distal hemorrhoid or cancer or prolapse in the distal rectum, as these are certainly issues at hand. It is the judgment of every Physician asked that pedunculated lesions, either hemorrhoidal or polyps, are very rare in the distal rectum, and they present very little, if any, risk of injury from using the F-Cal device because:
 - the way an impaction forms would push these lesions up against the rectal wall where the device wouldn't actually touch them because it is designed to remove the center of the impaction not the periphery.
 - even if it did encounter the lesion, the auger is protected inside the funnel of the device making it unlikely to engage the lesion.
 - When asked specifically if they had ever seen such a lesion when they retroflex their scope to examine the peri anal area at the end of a colonoscopy, none of them could remember seeing such a lesion.
 - To date no actual studies have been found that describe the distribution or type of lesions in the distal rectum.
 - ❖ This can reasonably lead one to conclude that the use of the F-Cal device offers little or no risk to cause injury to patients.

Additional Information & Next Steps

- More information is available on our website: www.f-cal.com
- If you are interested to be part of a Product Use study or purchasing the device for use in your facility, please contact Keith Gudeman to discuss next steps. Contact info:
- Mobile (248)444-8809
- Email keithgudeman@gmail.com

Be a part of setting a new standard of care for fecal impaction removal.



NOTES:
