Emerging Intraoperative Strategies for Reducing Surgical Site Infection Risk in Colorectal Surgery

What to Do When the Guidance Isn't Clear

Summary

Given that approximately half of surgical site infections (SSIs) are preventable according to the Centers for Disease Control and Prevention (CDC), SSI rates continue to be high, particularly in colorectal surgeries. More focus is needed on what hospitals can do to enhance SSI prevention bundles with research, expert consensus, and innovative new approaches.

The risk of SSI is higher in colorectal operations due to the high levels of contamination that occur during these surgeries. Therefore, intraoperative infection control measures focused specifically on wound-edge contamination should be evaluated for inclusion in colorectal SSI bundles and programs.

This paper offers recommendations on two critical areas of SSI prevention:

– Making existing SSI bundles more effective in infection prevention and control through enhanced standardization

– Expanding SSI bundles to incorporate emerging infection prevention technologies and methods when zero preventable SSIs have not been achieved

May 2018

Sue Barnes, RN, CIC, FAPIC
Independent Clinical Consultant
sueabarnes@gmail.com

Surgical Site Infection Risk in Colorectal Surgery

Experts estimate that up to 55% of all surgical site infections (SSI) are preventable.[1] This statistic is especially important for colorectal surgery patients who suffer a disproportionate number of surgical site infections. The average rate of all SSIs in the United States is 2%, which equates to 300,000 infected patients each year.[2] However, despite the best efforts of surgical teams, the SSI rate after colorectal procedures is much greater—between 15% and 30%.[3] One contributing factor is that entry into the lumen of the colon, either planned or unplanned, often results in contamination of abdominal cavity and wound edges, increasing the risk of colorectal SSI.[4] Another factor is that a lack of standardization in SSI prevention processes may add to the risk.[5] In addition, we know that SSI prevention bundles are often limited to those measures supported by randomized controlled trials, despite falling short of the goal of zero preventable infections.[6]

Even among elective surgical procedures, colon surgery is associated with the highest rate of SSI.[4] Globally this could become an even more significant problem in the future, as the percentage of people over the age of 65 is increasing, anticipated to grow from 6% (2000) to 16% by 2050. This is relevant because colorectal cancer requiring surgical intervention is the third most common cancer and advanced age is a risk factor.[7]

The Centers for Disease Control and Prevention (CDC), the American College of Surgeons (ACS), and the National Surgical Quality Improvement Program (NSQIP) categorize SSI based on the anatomic location of the infection: superficial incisional, deep incisional, and organ space.[8-10] Superficial infections involve the skin and subcutaneous tissues, deep infections involve the muscle and fascia, and organ/space infections are in the abdominal cavity (after colorectal surgery). This paper will address risk factors associated with superficial and deep surgical infection after colorectal surgical procedures and strategies to mitigate that risk.

THE PROBLEM

1. Colorectal SSI rates remain high
2. Contamination during the procedure contributes to high SSI
3. Lack of standardized prevention processes adds risk
4. Bundles limited to measures supported by randomized controlled trials despite falling short of goals

Patient and Economic Impact of SSI after Colorectal Surgery

The average excess cost associated with a colorectal SSI (superficial, deep, and organ space combined) is estimated to be $17,325.[11] In addition, these infections require a longer length of hospital stay and confer a higher mortality risk.[12-15] In one study of more than 500 patients, superficial SSI after colorectal surgery was associated with a 71.7% increase in initial hospital length of stay (7.9 vs. 4.6 days, P <.001).[3] These infections can also result in increased readmission rates with associated secondary hospital stays. In a recent study of more than 10,000 colorectal surgery patients, the 30-day readmission rate was 11.4%, and the 90-day readmission rate was 23.3%. The mean readmission length of hospital stay was 8 days.[16] Not as easily quantifiable is the patient suffering and family impact resulting from postoperative surgical infection.[17]

THE CONSEQUENCES

SSIs are costly to the hospital and have significant impact on the patient's quality of life

Role of Intraoperative Wound-Edge Contamination in Superficial and Deep SSI after Colorectal Surgery

Wound-edge contamination is the primary predisposing factor for superficial and deep colorectal SSI, which is further amplified by the virulence of the contaminating microorganisms and any compromise of the patient's host defenses.[4]

THE CONTAMINATION CULPRIT

Wound-edge contamination is the primary predisposing factor for incisional SSI in colorectal surgery

The greater the number of contaminating bacteria on the wound edges, the greater the probability of infection.[4] In open, lap-assisted, robotic, and completely laparoscopic abdominal procedures, bacteria can easily be transferred to the wound edges from hollow viscera. Consequently, gram-negative bacilli (e.g., Escherichia coli) and anaerobes (e.g., Bacteroides fragilis) are reported as the most common pathogens causing colorectal SSI.[18] There is, of course, an additional, much smaller risk from gram positives such S. aureus, which may be introduced from patient's skin flora remaining after skin prep or from the surgical team.[4]

In the past decade, SSI prevention efforts have been focused on improving compliance with evidence-based practices, such as those from the Surgical Care Improvement Project (SCIP).[3,19] Studies have demonstrated that improved outcomes can be achieved by applying these practices via a systematic approach or bundle.[11,20-22] However, despite all efforts to date, the SSI rate for colorectal cases in most locations remains high. Consequently, it may be prudent to consider enhancement of existing SSI prevention bundle elements and/or addition of new evidence-based bundle elements for high-risk procedures such as colorectal.

THE CALL TO ACTION

Consider enhancement of existing SSI prevention bundle elements and/or addition of new evidence-based bundle elements for high risk procedures

Enhancing SSI Prevention Specific to Colorectal Procedures

Standard SSI prevention efforts (typically applied in a bundle) to reduce the inoculum of bacteria that could cause infection after colorectal surgery cases include: appropriate surgical site skin preparation (reduces the risk of introducing bacteria at the time of incision), systemic prophylactic antibiotics (directed at bacteria that may contaminate the abdominal cavity and wound edges during a case), glucose control (to optimize leukocyte bactericidal activity), normothermia (to prevent triggering thermoregulatory vasoconstriction), use of mechanical bowel preparation in conjunction with the oral antibiotic bowel preparation (reduces the colonic bioburden, the source of bacteria which could result in wound-edge and visceral contamination because the bowel is intentionally opened as part of the planned operation), irrigation, and wound-edge protectors (reducing wound edge and visceral contamination during the surgical case).[4,9,19,20,23-26] However, professional guidance to ensure a standardized approach is lacking for most of these SSI prevention elements.[24,27] Additionally, guidance regarding application of emerging effective SSI prevention methods and technologies supported by less than randomized controlled studies – plus measures – is similarly lacking.

This paper will help to provide initial insight and recommendations regarding (1) standardization of key colorectal surgery SSI prevention bundle elements that are not clearly defined in published guidelines, and (2) introduction of innovative SSI prevention methods and technologies or "plus measures" for consideration when SSI prevention targets have not yet been achieved with the existing bundle.

Standardization of Key Colorectal Surgery SSI Prevention Bundle Elements

The following key elements are either done intraoperatively or are done preoperatively but have a direct impact on intraoperative contamination.

Preoperative Oral Mechanical Bowel Preparation (OMBP) and Oral Antibiotics

The recently published SSI Prevention Guidelines from the American College of Surgeons, World Health Organization, Society for Healthcare Epidemiology of America, and Wisconsin Public Health Council recommend the use OMBP followed by oral antibiotics before elective colorectal surgery. However, there is no agreement regarding the best protocol for bowel prep or the preferred type of oral antibiotic.[9,28-31]

Enhancing Standardization of OMBP and Oral Antibiotics

In the absence of a nationally recognized standard protocol for OMBP and oral antibiotics, at a minimum, it would be prudent to support a standardized approach among surgeons at a facility level. This may be best accomplished in collaboration among surgeon(s) with input from an Infectious Diseases physician specialist.

Preoperative Surgical Skin Preparation

Preoperative skin preparation begins at most locations with antiseptic patient bathing as supported by all recent SSI Prevention Guidelines except CDC.[9,28-31] Adhering to a scientifically proven, standardized process for preoperative bathing with either chlorhexidine gluconate (CHG) liquid or CHG impregnated bathing cloths has been proven to result in skin surface concentrations of CHG that are sufficient to inhibit or kill gram-positive or gram-negative surgical wound pathogens (16.5µg/cm2).[32]

In addition to preoperative antiseptic bathing, surgical skin preparation involves the antimicrobial solution applied to the planned incision area in a prescribed manner. The quality of skin preparation products used in the operating room has improved over the years, however, the application process is still subject to human error. A dual-agent skin prep product (alcohol plus iodine or CHG) is recommended by all recent SSI prevention guidelines as the most effective.[9,28-31] Studies focused on surgical skin preparation have reported that contaminants may remain after prep is completed, if not performed correctly or without the appropriate prep solutions.[33,34]

Enhancing Standardization of Preoperative Surgical Skin Preparation

- Ensure one of the following scientifically proven protocols for preoperative antiseptic bathing is provided to, and followed by, all colorectal patients:

    - Use a bottle containing 118 mL of 4% aqueous CHG for each of two showers: one the night before surgery, the second the morning of surgery. During each shower, pause for one minute after lathering and before rinsing.[32]

    – OR –

    - Use a total of six CHG-impregnated cloths: one for the neck and chest, wiping side to side including under breasts; one for the back; one for each arm and underarm; and one for each leg and groin. Allow to air dry and do not rinse off.[35]

- Validate surgical skin preparation application competency for nurses and/or technicians who are responsible for performing it.[36]

- Consider simulation as the method of competency training, which has been proven to be effective for retention of knowledge.[37]

Wound-Edge Protectors

Wound-edge protectors are designed with a plastic sheath attached to either a single ring or two rings, which secure the device and isolate the wound edges. This device additionally may provide retraction of the incision, improving visualization. These devices are intended to reduce wound-edge contamination during abdominal surgical procedures, such as colorectal.[28] Multiple recently published peer reviewed SSI Prevention guidelines have endorsed the benefit of wound-edge protectors for SSI risk reduction.[9,28-31] In some studies, the SSI rate with a single-ring wound-edge protector device has been reported to be as much as twice the rate compared to when a double-ring device was used.[28] Regardless of design, if the wound-edge protector is not inserted or removed correctly, injury and wound-edge contamination can result.[28]

Enhancing Standardized Use of Wound Edge Protectors

- Use only double-ring wound-edge protection devices.[28]
- Ensure that surgeons receive training on the use of wound-edge protectors, including the correct process for insertion and removal, to avoid wound-edge injury and contamination.[28]

Intraoperative Surgical Irrigation

Irrigation of wound edges and the abdominal cavity is done to remove contaminants, dead or damaged tissue, and wound exudate. As such, it has been suggested to be useful in reducing SSI risk.[23]

Among the most recent peer reviewed SSI prevention guidelines, there is no consensus on the topic of surgical irrigation.[8,9,28,30] As a result, there is great inconsistency with regard to the three primary irrigation variables (delivery method, volume, and solution additives), but there is an increasing body of evidence suggesting the benefit of various irrigation methods in reducing contamination/SSI risk.[23,27,39] It is important to evaluate different irrigation methods individually as opposed to as a heterogeneous group, since certain methods may show benefit more than others.

Enhancing Standardization of Intraoperative Surgical Irrigation

- Throughout the colorectal case, use sterile, normal saline for irrigation of abdominal cavity and wound edges to remove contaminants and debris.[27]

- At the end of the colorectal surgical case, prior to closure, consider trialing the use of an antiseptic irrigation solution applied to the abdominal cavity, with a one-minute pause after application, followed by rinsing to eliminate any remaining contaminants in the abdominal cavity (e.g., dilute povidone iodine and 0.05% CHG).[40-43]

Introduction of Product Innovations or Plus Measures

Innovation is important in advancing the efforts of surgical infection prevention programs. However, implementation of innovation by surgeons and other clinicians is often less than optimal. Regulatory and public focus on reducing infection rates and making healthcare safer provide a lever to support engagement of clinicians in considering innovations in surgical infection prevention. Infection Prevention professionals can play major roles in this translation via implementation science.[44]

Addition of Beyond the SSI Prevention Bundle "Plus" Elements

Consider addition of the following innovations during expansion of colorectal SSI prevention bundles when zero preventable infections have not been achieved with existing methods:

- Use of innovative sterile 0.05% CHG surgical irrigation solution at the end of colorectal cases, allowing one minute for antimicrobial effect prior to rinsing out, in order to inactivate contaminants in the abdominal cavity prior to closing.[45]

- Use of innovative device that combines wound-edge protection and irrigation, thereby supporting a standardized approach to both.[46,47]

DEFINITION OF A PLUS MEASURE

Infection prevention practices and products that are supported by less than category 1 level evidence, which can be considered when there is no associated risk to the patient, and to support the drive to zero sustained preventable infections.

Conclusions

Improving the overall reliability of complex systems has been an approach used effectively in manufacturing and airline industries to improve safety and outcomes. Applying this same reliability principle to health care has been an approach that has succeeded in reducing "defects" in care or care processes including infections, increasing the consistency with which appropriate care is delivered, and improving outcomes.[48]

CONCLUSIONS

1. It is time to consider enhancing SSI Prevention with inclusion of new technologies
2. Until sustained zero preventable colorectal SSI is achieved, expansion of bundles should be considered

Despite the best prevention efforts, surgical infection after colorectal procedures remains on average between 15% and 30%. This results in largely preventable excess costs to health care and suffering of patients and families. It is time to consider enhancing standardized application of existing SSI prevention standards with inclusion of new technologies.

The primary variable responsible for superficial and deep surgical infection in colorectal cases is contamination of wound edges. If the proven principle of reliable design (i.e., standardization) was applied to reduce wound-edge contamination, the result could be improved consistency of high quality care and reduced incidence of colorectal SSI. In addition, until zero preventable colorectal SSI is achieved, expansion of SSI prevention bundles should be considered.

About the Author

Sue A. Barnes RN, CIC, FAPIC is an independent clinical consultant, formerly the National Corporate IP Director at Kaiser Permanente. She is board certified in Infection Control and Prevention and was granted the designation of Fellow of the Association for Professionals in Infection Control and Epidemiology (APIC) in 2015.

This white paper is sponsored by Prescient Surgical as part of an education program on advances in intraoperative SSI prevention strategies. To learn more about CleanCision™ and Prescient Surgical, visit prescientsurgical.com

Questions, comments, and feedback on this whitepaper should be directed to Sue Barnes at sueabarnes@gmail.com or education@prescientsurgical.com

References

1. Umscheid CA, Mitchell MD, Doshi JA, Agarwal R, Williams K, Brennan PJ. Estimating the proportion of healthcare-associated infections that are reasonably preventable and the related mortality and costs. Infect Control Hosp Epidemiol. 2011;32(2):101–114.

2. Scott RD. The Direct Medical Costs of Healthcare-Associated Infections in U.S. Hospitals and the Benefits of Prevention. Centers for Disease Control and Prevention; Atlanta: 2009. http://www.cdc.gov/hai/pdfs/hai/scott_costpaper.pdf Accessed April 25, 2018.

3. Keenan JE, Speicher PJ, Thacker JKM, Walter M, Kuchibhatla M, Mantyh CR. The Preventive Surgical Site Infection Bundle in Colorectal Surgery an Effective Approach to Surgical Site Infection Reduction and Health Care Cost Savings. JAMA Surg. 2014; 149(10):1045–1052.

4. Fry DE. The Prevention of Surgical Site Infection in Elective Colon Surgery. Scientifica. 2013; 2013: 896297.

5. Amalberti R, Auroy Y, Berwick D, et al. Five system barriers to achieving ultrasafe health care. Ann Intern Med. 2005;142:756–764. [PubMed] [Reference list]

6. Burns PB, Rohrich RJ, Chung KC. The Levels of Evidence and their role in Evidence-Based Medicine. Plastic and reconstructive surgery. 2011;128(1):305-310.

7. Rasool S, Kadla SA, Rasool V, Ganai BA. A comparative overview of general risk factors associated with the incidence of colorectal cancer. Tumour Biol. 2013 Oct; 34(5):2469-76.

8. Berríos-Torres SI, Umscheid CA, Bratzler DW, Leas B, Stone EC, Kelz RR, Reinke CE, Morgan S, Solomkin JS, Mazuski JE, Dellinger EP, Itani KMF, Berbari EF, Segreti J, Parvizi J, Blanchard J, Allen G, Kluytmans JAJW, Donlan R, Schecter WP . Centers for Disease Control and Prevention Guideline for the Prevention of Surgical Site Infection, 2017. JAMA Surg. 2017;152(8):784–791. https://jamanetwork.com/journals/jamasurgery/fullarticle/2623725 Accessed April 25, 2018.

9. Ban KA, Minei JP, Laronga C, Harbrecht BG, Jensen EH, Fry DE, Itani KM, Dellinger EP, Ko CY, Duane TM. American College of Surgeons and Surgical Infection Society: Surgical Site Infection Guidelines, 2016 Update. J Am Coll Surg. 2017 Jan; 224(1):59-74.

10. Selby LV, Sjoberg DD, Cassella D, et al. Comparing Surgical Infections in NSQIP and an Institutional Database. The Journal of surgical research. 2015;196(2):416-420.

11. Wick EC, Hobson DB, Bennett JL, et al. Implementation of a surgical comprehensive unit–based safety program to reduce surgical site infections. J Am Coll Surg. 2012; 215(2):193-200.

12. Anderson DJ, Kirkland KB, Kaye KS, et al. Under-resourced hospital infection control and prevention programs: penny wise, pound foolish? Infect Control Hosp Epidemiol. 2007; 28(7):767-773.

13. Stone PW, Braccia D, Larson E. Systematic review of economic analyses of health care-associated infections. Am J Infect Control. 2005; 33(9):501-509.

14. Mahmoud NN, Turpin RS, Yang G, Saunders WB. Impact of surgical site infections on length of stay and costs in selected colorectal procedures. Surg Infect (Larchmt). 2009; 10(6):539-544.

15. Anthony T, Long J, Hynan LS, et al. Surgical complications exert a lasting effect on disease-specific health-related quality of life for patients with colorectal cancer. Surgery. 2003; 134(2):119-125.

16. Lutfiyya W, Parsons D, Breen J. A Colorectal "Care Bundle" to Reduce Surgical Site Infections in Colorectal Surgeries: A Single-Center Experience. The Permanente Journal. 2012; 16(3):10-16.

17. Andersson AE1, Bergh I, Karlsson J, Nilsson K. Patients' experiences of acquiring a deep surgical site infection: an interview study. Am J Infect Control. 2010 Nov; 38(9):711-7.

18. Reichman DE, Greenberg JA. Reducing Surgical Site Infections: A Review. Reviews in Obstetrics and Gynecology. 2009; 2(4):212-221.

19. Bratzler DW, Hunt DR. The Surgical Infection Prevention and Surgical Care Improvement Projects: national initiatives to improve outcomes for patients having surgery. Clin Infect Dis. 2006; 43(3):322-330.

20. Bull A, Wilson J, Worth LJ, et al. A bundle of care to reduce colorectal surgical infections: an Australian experience. J Hosp Infect. 2011; 78(4):297-301. 23.

21. Cima R, Dankbar E, Lovely J, et al; Colorectal Surgical Site Infection Reduction Team. Colorectal Surgery Surgical Site Infection Reduction Program: A National Surgical Quality Improvement Program–driven multidisciplinary single-institution experience. J Am Coll Surg. 2013; 216(1):23-33.

22. Hedrick TL, Heckman JA, Smith RL, Sawyer RG, Friel CM, Foley EF. Efficacy of protocol implementation on incidence of wound infection in colorectal operations. J Am Coll Surg. 2007; 205(3):432-438.

23. Norman G, Atkinson RA, Smith TA, et al. Intracavity lavage and wound irrigation for prevention of surgical site infection. The Cochrane Database of Systematic Reviews. 2017; (10):CD012234.

24. Edwards JP, Ho AL, Tee MC, et al. Wound protectors reduce surgical site infection: a meta-analysis of randomized controlled trials. Annals of Surgery. 2012; 256:53–59.

25. Jeon CY, Furuya EY, Berman MF, Larson EL. The Role of Pre-Operative and Post-Operative Glucose Control in Surgical-Site Infections and Mortality. Folli F, ed. PLoS ONE. 2012;7(9):e45616.

26. Lehtinen SJ, Onicescu G, Kuhn KM, Cole DJ, Esnaola NF. Normothermia to Prevent Surgical Site Infections After Gastrointestinal Surgery: Holy Grail or False Idol? Annals of Surgery. 2010;252(4):696-704.

27. Barnes S, Spencer M, Graham D, Johnson HB. Surgical wound irrigation: a call for evidence-based standardization of practice. Am J Infect Control. 2014 May; 42(5):525-9.

28. Allegranzi B, Zayed B, Bischoff P, Kubilay NZ, de Jonge S, de Vries F, Gomes SM, Gans S, Wallert ED, Wu X, Abbas M, Boermeester MA, Dellinger EP, Egger M, Gastmeier P, Guirao X, Ren J, Pittet D, Solomkin JS; WHO Guidelines Development Group. New WHO recommendations on intraoperative and postoperative measures for surgical site infection prevention: an evidence-based global perspective. Lancet Infect Dis. 2016 Dec;16(12):e288-e303 with Appendix 18 Wound Protectors.

29. Anderson DJ, Podgorny K, Berrios-Torres SI, Bratzler DW, Dellinger EP, Greene L, et al. Strategies to prevent surgical site infections in acute care hospitals: 2014 update. Infect Control Hosp Epidemiol. 2014; 35(6):605-27.

30. Edmiston C. et al. "Wisconsin Division of Public Health Supplemental Guidance for the Prevention of SSI: An Evidence Based Perspective". January 2017 https://www.dhs.wisconsin.gov/publications/p01715.pdf Accessed April 25, 2018.

31. Fry Donald E. "Antimicrobial Bowel Preparation for Elective Colon Surgery". Surgical Infections. 20 May 2016. Vol. 17, No. 3.

32. Edmiston CE Jr, Krepel CJ, Seabrook GR, Lewis BD, Brown KR, Towne JB. Preoperative shower revisited: can high topical antiseptic levels be achieved on the skin surface before surgical admission? J Am Coll Surg. 2008 Aug;207(2):233-9.

33. Ostrander RV, Brage ME, Botte MJ. Bacterial skin contamination after surgical preparation in foot and ankle surgery. Clin Orthop Relat Res. 2003 Jan;(406):246-52.

34. Hort KR, DeOrio JK. Residual bacterial contamination after surgical preparation of the foot or ankle with or without alcohol. Foot Ankle Int 2002;23:946-8.

35. CHG cloths for Pre-op bathing example: https://mydoctor.kaiserpermanente.org/ncal/Images/Preparing%20The%20Skin%20before%20Surgery%20v6_tcm75-823597.pdf Accessed April 25, 2018.

36. Stobinski J. Perioperative nursing competency. AORN J. 2008;88(3):417- 436.

37. Lateef F. Simulation-based learning: Just like the real thing. Journal of Emergencies, Trauma and Shock. 2010;3(4):348-352.

38. Berrios-Torres SI, Umscheid CA, Bratzler DW, Leas B, Stone EC, Kelz RR, et al. Centers for Disease Control and Prevention Guideline for the Prevention of Surgical Site Infection, 2017. JAMA Surg. 2017.

39. Mueller TC, Loos M, Haller B, Mihaljevic AL, Nitsche U, Wilhelm D, et al. Intra-operative wound irrigation to reduce surgical site infections after abdominal surgery: a systematic review and meta-analysis. Langenbecks Arch Surg. 2015;400(2):167-81.

40. Fournel I et al. "Meta analysis of intraoperative povidone–iodine application to prevent surgical site infection". IBJS Volume 97, Issue 11, November 2010; pp 1603-1613.

41. Bondar VM, Rago C, Cottone FJ. Chlorhexidine lavage in the treatment of experimental intra-abdominal infection. Arch Surg 2000;135:309-314.

42. Shams WE, Hanley GA, Orvik A, et al. Peritoneal lavage using chlorhexidine gluconate at the end of colon surgery reduces postoperative intra-abdominal infection in mice. J Surg Res 2015; 195:121-127.

43. Edmiston CE, Leaper D. Intraoperative surgical irrigation of the surgical wound: What does the future hold – Saline, antibiotic agents or antiseptic agents? Surg Infect 2016; 17: 656-664.

44. Saint S, Howell JD, Krein SL. Implementation Science: How To Jumpstart Infection Prevention. Infection control and hospital epidemiology : the official journal of the Society of Hospital Epidemiologists of America. 2010;31(Suppl 1):S14-S17.

45. Edmiston C. et al. "Considering a new domain for antimicrobial stewardship: topical antibiotics in the open surgical wound". AJIC 45 (2017) 1259-66.

46. Papaconstantinou, H.T., et al., A Novel Wound Retractor Combining Continuous Irrigation and Barrier Protection Reduces Incisional Contamination in Colorectal Surgery. World Journal of Surgery, 2018.

47. Martens K. "FDA Clears New Surgery Infection Control System". JD Supra Medical Device Blog. March 5, 2018. https://www.jdsupra.com/legalnews/fda-clears-new-surgery-infection-95182/ Accessed April 25, 2018.

48. Institute of Healthcare Improvement (IHI) White Paper on Reliable Design: http://www.ihi.org/resources/Pages/IHIWhitePapers/ImprovingtheReliabilityofHealthCare.aspx Accessed April 25, 2018.