Appendix 2b: Studies related to double-ring wound protectors

Author, year, reference	Study design/setting	Population, type of surgery, approach, timing	Type of wound included	Intervention	Comparison	Outcome - SSI definitions	Results Incisional – SSI rate	Limitations
Cheng, 2012 *(8)*	RCT single centre university hospital November 2008-November 2010 Malaysia	64 patients Colorectal laparotomy - elective Bowel preparation only for ultra-low anterior resection with protective ileostomy.	Group: clean-contaminated	n=34 Alexis-O double-ring WP (single size up to 17 cm in length)	n=30 Wound packing and standard retractor	Incisional SSI: CDC criteria 30-day follow-up.	I: 0/34 (0%) C: 6/30 (20%) *P*=0.006 OR not provided Lost to follow-up: 8	3 cases per month in a a university hospital department: restricted/low rate of recruitment. The number of procedures per surgeon is not provided: potential bias might be derived from such a possible imbalance if poor performers are in the standard group. A maximum incision length of 17 cm allowed for in the WP. No specific limitation for the standard procedure. No statement about adverse events.

								No statement about handling of patients lost to follow-up/intention-to-treat.
Horiuchi, 2007 *(9)*	RCT single centre university hospital September 2003-August 2004 Japan	221 patients Gastrointestinal surgery laparotomy - not specified They stated "open non-traumatic colorectal and gastric surgery". Excluded: gastrointestinal perforations. Groups: gastric colorectal, hepato-pancreato-biliary other. Antibiotic prophylaxis standardized according to type of surgery. Bowel	Group: clean-contaminated	n=111 Alexis®-O double-ring WP (Applied Medical, Rancho Santa Margarita, CA, USA) Gastric (n=37) colorectal (n=40) hepato-pancreato-biliary (n=23) other (n=11)	n=110 Wound margin left untreated Gastric (n=36) colorectal (n=52) hepato-pancreato-biliary (n=18) other (n=4)	Incisional SSI: CDC criteria Follow-up unclear	SSI - incisional I: 0/111 (0%) C: 9/110 (8.1%) *P*= 0.002 SSI total I: 8/111 (7.2%) C: 16/110 (14.5%) SSI total: I: 8/111 (7.2%) C: 7/110 (6.3%) Analysis for colorectal surgery: difference for incisional SSI found. I: 0/40 (0%) C: 7/52 (13.4%) *P*= <0.05 Length of stay: I: 34.4 days C: 33.8 days Deaths following anastomotic	No method of concealment described or follow-up period. Within the colorectal surgery: no description of the degree of wound contamination.

		preparation for colorectal surgery.					leakage: I: 2 vs. C: 1	
Lee, 2009 *(10)*	RCT single centre community teaching hospital May 2006- May 2008 USA	109 patients Appendiceal surgery McBurney laparotomy - urgent Groups were comparable for "degree of appendicitis at time of operation". Antibiotic regimen was standardized (preoperative, simple application, complicated application, ruptured).	Group: dirty	n=61 Alexis®-O double-ring WP (small size, 2.5-6 cm) "..degree of appendicitis at time of operation": acute (n=28) suppurative (n=11) gangrenous (n=7) perforated (n=15)	n=48 Regular wound retractors "..degree of appendicitis at time of operation": acute (n=23) suppurative (n=7) gangrenous (n=4) perforated (n=14)	Incisional SSI: not CDC criteria "significant subcutaneous SSI" necessitating wound opening or treatment with antibiotics. Included patients prescribed a separate course of antibiotics after discharge from the hospital. Follow-up: 21 days	I: 1/61(1.6%) C: 7/48 (14.6%) *P*=0.02 I: Perforated (n=1) C: Acute (n=2) Suppurative (n=1) Perforated (n=4) OR not provided Lost to follow-up: 1 Patients withdrawn: 3	Study SSI definition: it is quite common that patients operated for a complicated appendicitis receive an additional antibiotic treatment, regardless of the postoperative outcome. However, there is a risk that a patient with an uneventful postoperative course could be classified in the SSI incisional infection group because of the postoperative antibiotic treatment. No description of the size of the

								incision. No data on adverse events. No statement about handling of patients lost to follow-up/intention-to-treat.
Reid, 2010 *(14)*	RCT multicentre 4 hospitals January 2007-June 2008 Australia	130 patients (mean age, 63 years) Colorectal (benign and malign) surgery. Laparotomy - elective	Group: clean-contaminated	n=64 Alexis®-O double-ring WP	n=66 Regular wound retractors Of note, it is not clear if some additional protection was used and placed in between the regular retractors and the wound incision	Incisional SSI: CDC criteria Follow-up: 30 days	I: 3/64 (4.69%) C: 16/66 (22.7%) *P*=0.004 OR not provided Number needed to treat to prevent 1 SSI: 6 (95% CI: 3.4-15) Absolute risk reduction of 18.04% by employing a WP Mean length of stay: I: 13.7 days C: 12.3 days Lost to follow-up: 5 (3 protocol violations, 2	8 different surgeons were involved; the proportion of operations was unequally distributed among all surgeons. Bowel preparation plus surgical technique depending on surgeon. 5 patients excluded from the analysis; 2 deaths and 3 protocol violations. No clear statement regarding death as an adverse event. No statement about handling of patients lost to

							deaths)	follow-up/intention-to-treat. The authors report one organ/space infection in each group and 2 anastomotic leaks in the intervention group (unclear whether the patients had also incisional SSI or not).
Theodoridis, 2011 *(16)*	RCT single centre university hospital January 2008-July 2008 Greece	231 patients C-section Pfanestiel laparotomy - elective or urgent-emergent Both arms have the same antibiotic prophylaxis after cord clamping - 2 doses up to a maximum of 24 hours	Group: clean-contaminated	n=115 Alexis®-O double-ring WP	n=116 Regular wound retractors (no additional potection provided)	Incisional SSI: not CDC criteria Wound dehiscence, pain or tenderness at the lower abdomen, localized swelling, redness and heat or purulent discharge from the wound. Follow-up unclear.	I: 0/115 (0%) C: 3/116 (2.6%) *P*: 0,006 No OR provided	Unclear process of randomization and blinding. No data are provided on follow-up, adverse events, intention-to-treat analysis and blind assessment.

SSI: surgical site infection; RCT: randomized controlled trial; WP: wound protector; CDC: Centers for Disease Prevention and Control; I: intervention; C: control; SSI: surgical site infection; OR: odds ratio; CI: confidence interval.