Appendix 2a: Studies related to single-ring wound protectors

Author, year, references	Study design/setting	Population, type of surgery, approach, timing	Type of wound included	Intervention	Comparison	Outcome - SSI definitions	Results	Limitations
Baier, 2012 *(7)*	RCT single centre university hospital. Germany	199 patients Colorectal for malign and benign colorectal diseases. No appendectomy or ostomy reduction. Laparotomy and laparoscopy-assisted surgery. Elective antibiotic prophylaxis, skin preparation and sterile draping were standardized.	Groups: 1. clean-contaminated 2. contaminated 3. dirty	n=98 3M Steri-Drape™ (3M, St Paul, MN; USA) with ring (3 sizes according to the length of the incision).	Standard measures and wet cloth towel (n=101)	Incisional CDC criteria Follow-up 30 days (early discharge patients contacted by telephone at day 30)	I: 20/98 (20%) (superficial SSI: 17/98; deep SSI: 3/98) C: 30/101 (29.7%) (superficial SSI: 22/101; deep SSI: 8/101) *P* > 0.05 for all SSIs. OR not provided Lost to follow-up: 33 In a subgroup of patients with contaminated or dirty surgery (n=116): I: 10/116 C: 23/116 *P* <0.05 In a multivariate analysis, wound classification was not a a risk factor.	Underpowered study: the authors calculated the sample size from a study with 3 times more patients and an expected high effect of 75% SSI decrease. 33 previously included patients were also excluded from the analysis because of reoperation/ complications different from SSI. The authors simply removed them from the analysis. No intention-to-treat analysis, no reporting of adverse events.

Brunet, 1994 *(17)*	Quasi-RCT single centre November 1991-November 1992 France	149 patients Abdominal - laparotomy - elective/urgent.	Groups: 1. clean 2. contaminated 3. dirty	n=73 Adhesive plastic with ring (3 sizes to adequately encompass the incision).	n=76 Not specified	Incisional SSI: non-CDC criteria; pus oozing from the wound. Follow-up: up to 1 month after surgery.	I: 6/73 (8.2%) C: 18/76 (23.7%) *P*=0.01 No OR or RR reported SSI rate per group: 1: 0/17 (0%) vs. 3/15 (20%) *P*=0.09 2: 5/50; 10% vs. 10/53 (18.9%) *P*=0.2 3: 1/6; 17% vs. 5/8 (62.5%) *P*=0.12	Published in a non-indexed journal. Although there are significant differences, the quality of the study is poor and adverse events and standard measures are not specifically described. Two patients excluded because of technical difficulties in placing the wound ring protector, but unclear if patients were removed from the analysis. Antibiotic prophylaxis was given in elective cases only for colorectal procedures. No significant differences between groups, probably because the

								study was underpowered.
Mihaljevic, 2014 *(11)*	RCT multicentre 16 hospitals September 2010-November 2012 Germany	546 patients Mean age, 68 years Abdominal – laparotomy - elective.	Groups: *A priori* 1. clean 2.clean-contaminated (clean, clean-contaminated, contaminated and dirty at the final analysis)	n=274 3M Steri-Drape™ with ring.	n=272 Surgical towels	SSI: CDC criteria Follow-up: external monitoring. Up to 45 days fixed (2,4,6 and 8) and in between periods (10 to 14 and 30 to 45). Lost to follow-up: 46 (all included in the intention-to-treat analysis). Overall mortality (deaths): I: 7 C: 4 Not attributable to study.	Overall SSI **Intention-to-treat analysis** I: 53/300 (17.7%) C: 74/294 (25.5%) OR: 0.64 (95% CI : 0.43-0.95) *P*=0.026 **Complete case analysis** I: 27/274 (9.9%) C: 52/272 (19.1%) OR: 0.46 (95% CI: 0.28-0.76) *P*=0.002 **Per protocol analysis** I: 25/240 (10.4%) C: 52/267 (19.5%) OR: 0.48 (95% CI: 0.29-0.8) *P*=0.005 **Subgroup analysis:** for clean contaminated/	No information about how surgeons and the surgical team (nurses, assistants) handle surgical field protectors /towels when contaminated at some point during the surgical procedure.

							contaminated I: 26/225 (11.6%) C: 47/221 (21.3%) OR: 0.48 (95% CI: 0.29-0.81) *P*=0.006	
Pinkney, 2013 *(12)*	RCT multicentre 21 hospitals February 2010-January 2012 UK	735 patients Median age: I: 66.4 years C: 64.2 years Abdominal Laparotomy - elective/urgent	Groups: 1. clean 2. clean-contaminated 3. contaminated 4. dirty	n=369 (382 randomized; 376 received laparotomy; 7 lost to follow-up.) 3M Steri-Drape™ with ring (3 sizes available).	n=378 (378 randomized; 373, received laparotomy, 7 lost to follow-up.) Surgical towels (surgeon decision)	Incisional SSI (superficial): CDC criteria. Follow-up: on days 5 to 7 or at discharge, then on days 30 to 33. For those patients unable to come to the hospital, home visits were planned. Among the total patients initially assessed for eligibility, 118 were excluded (reasons well defined) prior to randomization. Lost to follow-up: 14 (7 in each group).	I: 91/369 (24.7%) C: 93/366 (25.4%) OR: 0.97 (95% CI: 0.69-1.36) *P*=0.85 Assuming the maximum benefit from the intervention in *post hoc* sensitivity analysis: OR: 0.77 (95% CI: 0.54-1.09) *P*=0.14 SSI rate (degree of wound contamination) 1: 8/24 (33.3%) C: 7/29 (24.1%) **2**: I: 61/269 (22.7%) C: 63/263 (24%) **3**: I: 10/48; (20.8%)	SSI not classified other than superficial. Authors reported the rate of superficial incisional infection; no data provided on the overall SSI rate. No information about how surgeons and surgical team (nurses, assistants) handle visibly contaminated surgical field protectors in either group.

							C: 15/48 (31.3%) **4**: I: 12/28 (42.9%) C: 7/25 (28%) Length of stay (median of days): I: 9 (IQR: 6-15) C: 9 (IQR: 6-14) *P*=0.83 Overall mortality: no difference I: 8 (2.13%) C: 12 (3.21%)	
Redmond, 1994 *(13)*	RCT single centre university hospital Ireland	213 patients Mean age: 60 years Gastrointestinall aparotomy - elective/urgent. Antibiotic prophylaxis and skin preparation standardized.	Groups: 1. clean-contaminated 2. contaminated 3. dirty	n=102 WP not specified, poor description.	n=111 “received no protection”.	Incisional SSI: non-CDC criteria; purulent discharge or bacterial growth in wound samples. Follow-up at postoperative days 5-10 and 30.	I: 11/102 (10.8%) C: 27/111 (24.3%) *P*<0.05 OR not provided SSI rate per group: **1**: I: 6/75 (8%) C: 9/85 (10.58%) **2**: I: 3/21 (14.28%) C: 10/18 (55.5%) **3**: I: 2/6 (33.3%) C: 8/8 (100%)	Study published as an abstract A great amount of information on the methodology is lacking.

Sookhai, 1999 *(15)*	RCT, single centre, university hospital Ireland	352 patients Abdominal laparotomy- not specified Antibiotic prophylaxis and skin preparation standardized.	Groups: 1. clean-contaminated 2. contaminated 3. dirty	n=170 Single-ring WP "wound protector with a plastic ring placed inside the peritoneal cavity" – "impermeable plastic drape with four adhesive patches".	n=182 No WP	Incisional SSI: non-CDC criteria Presence of a purulent discharge, a culture positive at discharge, pain/tenderness, localized swelling, erythema or cellulitis occurring within 30 days of surgery. 30-day follow-up.	I: 23/170 (13.5%) C: 54/182 (29.6%) OR adjusted for degree of wound contamination: 0.31 (95% CI: 0.16-0.60) *P* <0.001 OR for each group: **1**: 0.52 (95% CI: 0.22-1.20) I: 9/129; C: 17/134 **2**: 0.16 (95% CI: 0.05-0.48) I: 8/33 C: 20/30 **3**: 0.18 (95% CI: 0.01-2.31) I: 6/8 C: 17/18	Not indicated how patients lost to follow-up were handled-RCT published as a letter in *The Lancet*. Randomization sequence generation not defined. Intention-to-treat analysis not performed.

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; RR: risk reduction; IQR: interquartile range.