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The Results

Using technology to help fight infection

HCAI Technology Innovation Programme
Showcase Hospitals report number 7
InteguSeal[®]



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The Healthcare Associated Infections (HCAI) Technology Innovation Programme

The basic ways of preventing and reducing healthcare associated infections (HCAs) are largely unchanging. The principal strategies for combating HCAs are those associated with hand hygiene/aseptic techniques, prudent antibiotic prescribing and good clinical practice. However, new technologies and equipment can support these strategies by helping get things done differently, more swiftly or more reliably.

The Department of Health is funding an HCAI Technology Innovation Programme¹. The Programme aims to

- Speed up the development and adoption of technologies to further help combat HCAs
- Identify which new technologies provide the best value and will have the most impact

The Showcase Hospitals Programme

In 2004 the Department of Health set up the Rapid Review Panel (RRP) to “provide a prompt assessment of new and novel equipment, materials and other products that may be of value to the NHS in improving hospital infection control and reducing hospital acquired infection”. The RRP does not undertake any product trials itself but makes recommendations based on written evidence provided by industry.² The highest recommendation (Recommendation 1) is

Basic research and development, validation and recent in use evaluations have shown benefits that should be available to NHS bodies to include as appropriate in their cleaning, hygiene or infection control protocols.

As part of the HCAI Technology Innovation Programme, technologies which have gained a RRP Recommendation 1 are being placed in up to 8 Showcase Hospitals around the country for periods up to six months during which time a detailed evaluation of their in-use and economic features along with adoption characteristics is undertaken. The current Showcase Hospitals are Calderdale and Huddersfield NHS Foundation Trust, Central Manchester University Hospitals NHS Foundation Trust County Durham and Darlington NHS Foundation Trust, Imperial College Healthcare NHS Trust, Mid Essex Hospital Services NHS Trust, Southampton University Hospitals NHS Trust, The Lewisham Hospital NHS Trust and The Royal Wolverhampton Hospitals NHS Trust.

These are service evaluations, as defined by the National Patient Safety Agency’s National Research Ethics Service, and do not therefore require Research Ethics Committee review.³

¹ For further information on the Programme see <http://www.clean-safe-care.nhs.uk/index.php?pid=28>

² For more information on the Rapid Review Panel see <http://www.hpa.org.uk/ProductsServices/InfectiousDiseases/ServicesActivities/RapidReviewPanel/rapAboutRRP/>

³ See leaflet on defining research at <http://www.nres.npsa.nhs.uk/news-and-publications/publications/general-publications/#leaflets>

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Showcase Hospitals report number 7

InteguSeal®

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Executive summary

The Department of Health has set up a Rapid Review Panel (RRP) to assess new and novel technologies and consider their potential for reducing hospital infections. As part of the Department's Healthcare Associated Infections (HCAI) Technology Innovation Programme, technologies that have received an RRP1 recommendation ("basic research and development, validation and in-use evaluations have shown benefits that should be available to NHS bodies") have been placed in selected Showcase Hospitals for review of their acceptability in everyday use and to gather information that may be useful for other hospitals.

InteguSeal[®] is a microbial barrier which locks down bacteria and seals and immobilises dangerous pathogens, thus potentially reducing the risk of skin flora contamination throughout a surgical procedure. The product is applied to the skin at the point of surgical incision and the liquid bonds to the skin. InteguSeal[®] was awarded Rapid Review Panel (RRP) recommendation 1 in 2008.

InteguSeal[®] was used in eight Showcase Hospitals for three to five months. Surgeons' and patient opinions were generally favourable, though opinions were divided as to whether the drying time is satisfactory.

InteguSeal[®] is used in addition to standard pre-operative skin preparation and therefore constitutes an additional cost, which may, however, be offset by reduced numbers of surgical site infections. A template business case has been produced.

Keywords: surgical site infections, HCAI, InteguSeal[®], Rapid Review Panel

Introduction

This report sets out the findings from an evaluation in NHS Showcase Hospitals of the in-use and economic features and adoption characteristics of InteguSeal®.

The Rapid Review Panel which assesses new and novel products which may help infection prevention and control has concluded that basic research and development, validation and recent in use evaluations have shown benefits that should be available to NHS bodies to include as appropriate in their cleaning, hygiene or infection control protocols.

The objective of this document is to help Directors of Infection Prevention and Control and other staff to decide whether they should consider InteguSeal® as part of their trust's strategy to reduce healthcare associated infections.

The problem

Surgical site infection

Surgical site infections (SSIs) are defined as infections occurring up to 30 days after surgery (or up to one year after surgery in patients receiving implants) and affecting either the incision or deep tissue at the operation site. Despite improvements in prevention, SSIs remain a significant clinical problem as they are associated with substantial mortality and morbidity and impose severe demands on healthcare resources.^[1] SSIs account for 15% of all HCAs and are estimated to at least double the length of hospital stay(LOS).^[2] Data from the Health Protection Agency shows that the postoperative LOS is longer for patients with SSI, and when adjusted for other factors influencing LOS, the extra LOS due to SSI ranges from 3.3 days for abdominal hysterectomy to 21.0 days for limb amputation, and at least nine days for the other surgical categories. The additional cost attributable to SSI ranges from £959 for abdominal hysterectomy to £6103 for limb amputation ^[3]

The high morbidity and mortality along with the additional costs associated with SSIs have led to the adoption of strategies that are intended to reduce the incidence of SSI. These strategies include administration of prophylactic antibiotics, use of antiseptic solutions for skin preparation, and the use of sterile disposable materials.

Microbial contamination of the surgical site is a likely precursor of SSI. This is of particular concern for clean wounds where contamination must have originated outside the wound. It is estimated that 1% to 5% of clean surgical procedures performed will result in an SSI.^[4] Consequently, pre-operative skin preparation is intended to render the skin as free as possible from endogenous bacteria that may enter the surgical wound. Although skin disinfection prior to surgery drastically reduces the number of bacteria on the skin's surface, re-colonisation with bacteria from deeper skin layers and hair follicles may occur during the operation^[5]

The product

InteguSeal®

InteguSeal® (see Figure 1) is a microbial barrier which locks down bacteria and seals and immobilises dangerous pathogens, including MRSA, *S. epidermidis* and *E. coli*, thereby potentially reducing the risk of skin flora contamination throughout a surgical procedure. The product is applied to the skin, using the special applicator, at the point of surgical incision and the liquid bonds with the skin forming a barrier that protects against skin flora migration into the surgical incision. The product is designed to be left on the skin and gradually wear away and it is not therefore necessary to remove it prior to wound closure or following completion of the surgical procedure. InteguSeal can be used in conjunction with antimicrobial incise drapes and is compatible with iodophors, 2% Chlorhexidine Gluconate (CHG) and isopropyl alcohol. InteguSeal® is marketed by Kimberly Clark.

The product is available in three sizes:

IS50 - for small surgical sites (up to 12cm x 25cm)

IS100 - for small-to-medium surgical sites (up to 25cm x 25cm)

IS200 - for larger areas (up to 25cm x 50cm)

In this evaluation there was an almost 50:50 split between IS100 and IS200 in terms of the size used.

Kimberly-Clark state that InteguSeal® meets stringent clinical safety guidelines and that the product is:

- Non-flammable
- Latex-free
- Non-irritating
- Non-cytotoxic
- Not a skin sensitizer
- Non-clastogenic
- Non-mutagenic
- No acute systemic toxicity.

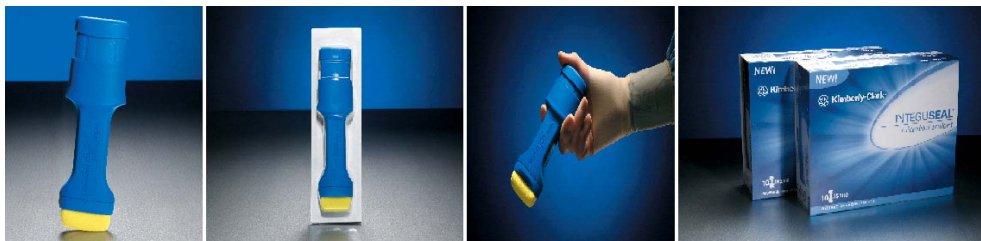


Figure 1 – InteguSeal®

InteguSeal® was awarded Rapid Review Panel (RRP) recommendation 1 in 2008.

The knowledge base

What was known before this evaluation

InteguSeal contains n-butyl cyanoacrylate that rapidly polymerises in the presence of water (specifically hydroxide ions) forming long, strong, chains, joining the bonded surfaces together.⁶

The application of the cyanoacrylates onto the skin immobilises the microorganisms present. Resistance is unlikely to develop to cyanoacrylates as the microorganisms cannot multiply, mutate, or adapt when immobilised.⁷

Several publications have appeared in peer-reviewed journals regarding the efficacy of InteguSeal. A prospective, randomised, multicentre clinical trial was undertaken at a medical centre in the United States on patients undergoing elective open inguinal hernia repair. The results of the study found that patients treated with InteguSeal were more likely to have no bacterial cells found in the wound than the control participants (47% vs 31% P=0.04).⁸

During a study performed in Germany, 910 patients underwent cardiac surgery. The standard institutional preoperative preparation was performed in 721 patients (control group), while 189 patients received an additional microbial sealant (InteguSeal[®]). A decrease of SSI in the InteguSeal[®] group 1.1% (n=2) compared with the control group 4.6% (n=33) demonstrated a significant (p<0.025) reduction of surgical site infections.⁹

The evaluation

How the evaluation was done

As part of the Showcase Hospitals programme, InteguSeal[®] was introduced for three to five months in selected NHS hospitals with the aim of evaluating its in-use features and adoption characteristics. The objectives were

- to identify if the use of InteguSeal[®] is acceptable to users/surgeons.
- to look at ways of engagement between the surgical teams and the suppliers, and record which are the most effective.
- to assess the in-use characteristics of InteguSeal[®] and identify its range of use, which surgical specialities it is deployed in and consistency of its use.
- to identify those features of InteguSeal[®] which may encourage adoption or be a barrier to entry into the NHS

Before the trial began, staff from Kimberly-Clark held training meetings with theatre surgical staff. Conferences also took place with InteguSeal[®] representatives in attendance and “drop in” sessions were organised with the purpose being to inform and train as many theatre staff as possible. Information sheets were distributed and posters were placed in positions

around the theatre so that surgeons were reminded about using InteguSeal® and of its application procedure.

Information was gathered on the staff who had been approached to use the product, their willingness to agree to participating in the evaluation, and the steps that were taken to facilitate the introduction of the product. Information was also captured on the steps that the representatives from Kimberly Clark had taken to aid in the uptake of the product and the training they provided.

Further information was gathered in particular on usage of the product, attitudes towards how the introduction of the product had impacted on the surgical process, and if there was a willingness to continue to use the product after completion of the evaluation.

Who used InteguSeal®?

73 out of 87 surgeons who were approached agreed to use the product as part of the evaluation, but, as the evaluation progressed, usage spread through “word of mouth” and at the end of the evaluation 95 surgeons responded to the post use survey. Figure 2 shows that 23% of staff came from orthopaedic departments and 20% from cardiac departments, with 17% from obstetrics and gynaecology.

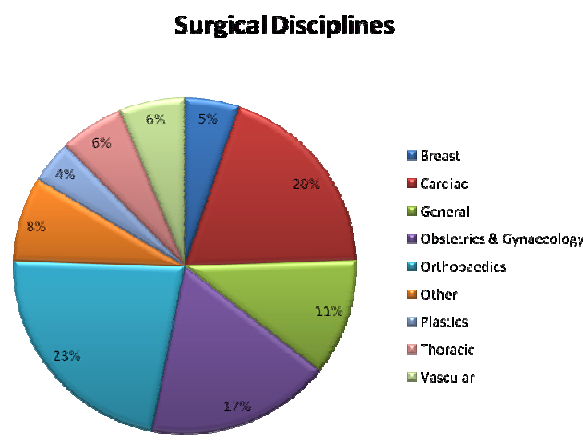


Figure 2 – Breakdown of Responding Surgeons by Discipline

For what procedures was InteguSeal® used?

Over 65% of respondents said that InteguSeal® had not been used for **all** of their procedures. The surgeons’ responses suggest that they made a decision on when to use the product based on the nature of the surgery being performed. For example, there appears to be a willingness among surgeons to use it for caesarean sections but not in cases of emergency surgery. It is possible therefore to conclude from this that the surgeons appeared to have

faith in the product, but made personal decisions on which cases were suitable for its use. Furthermore, anecdotal feedback on the usage of the product may increase once the product becomes part of normal surgical practice and subsequently more familiar to the surgeons.

How acceptable was the product to staff?

As can be seen from figure 3, the practical aspects of InteguSeal® were evaluated very positively by the surgeons at the showcase hospitals with 95% of those who expressed an opinion agreeing or strongly agreeing that InteguSeal® was easy to use. The characteristics that most impressed the users were the flow of the product onto the sponge (94% agreed or strongly agreed that this was appropriate), the ease of application of the product onto the skin (91% agreed or strongly agreed on the ease) and lack of compatibility issues (90% agreed or strongly agreed with this statement). In addition 86% of respondent surgeons agreed or strongly agreed that the target area was adequately covered and 84% agreed or strongly agreed that they had not experienced any adverse events. However, views on whether the drying time was satisfactory were almost evenly divided, with 52% of respondents agreeing or strongly agreeing.

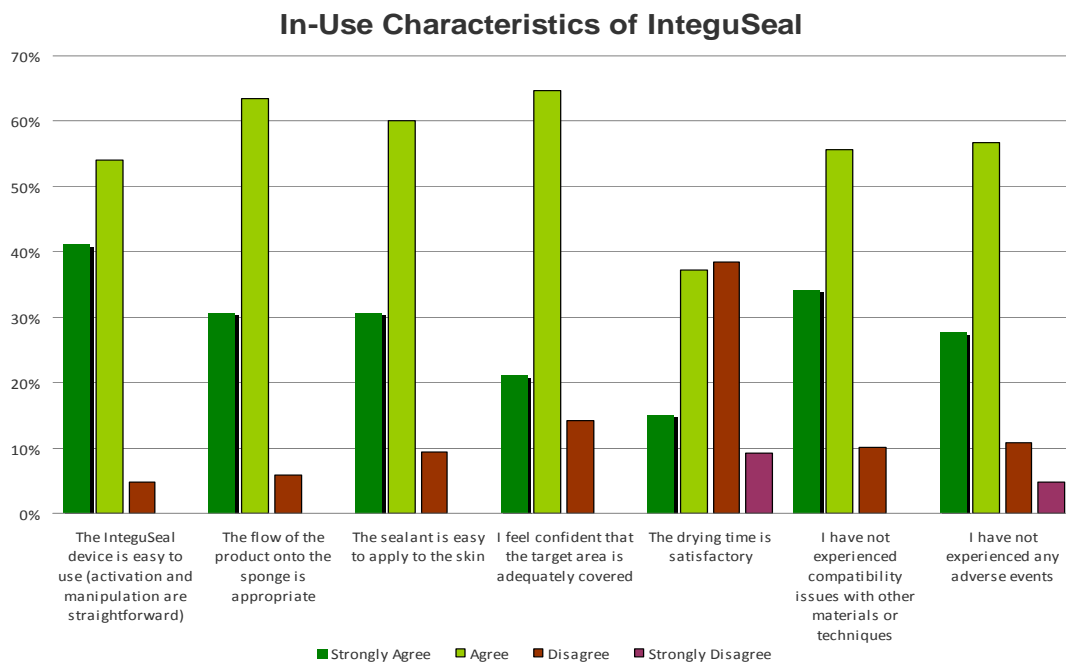


Figure 3 – Surgeons’ Evaluation of InteguSeal®

Figure 4 shows that participating surgeons generally assessed InteguSeal® positively. 74% agreed or strongly agreed that using InteguSeal® had been a positive experience. However, rather fewer of them (64%) were confident that that the product could help to reduce surgical site infections.

Surgeons' Views on InteguSeal

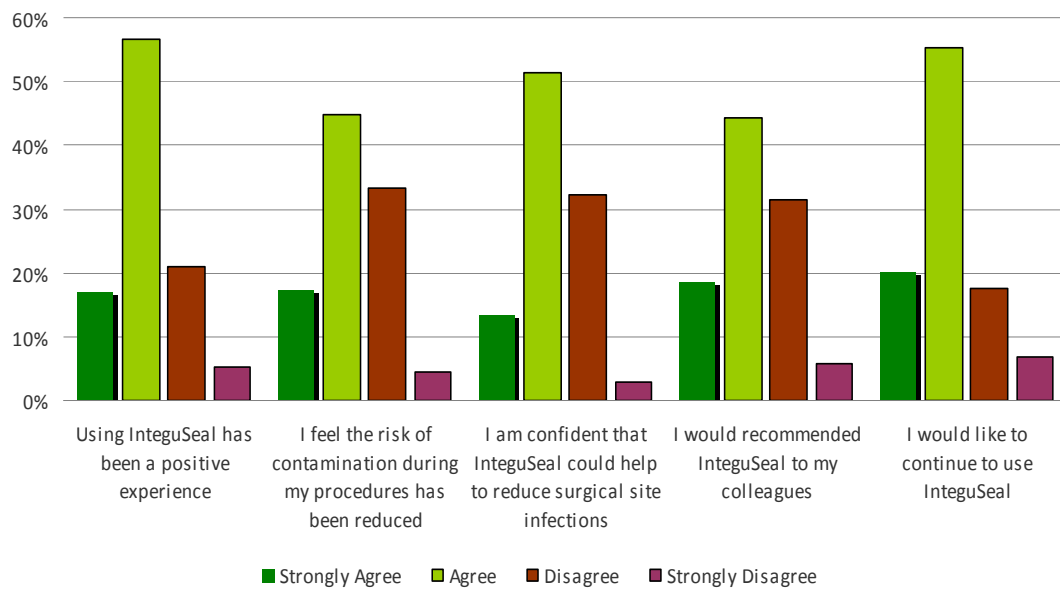


Figure 4 – Surgeons' Views on InteguSeal®

How acceptable was the product to patients?

Patients were not asked directly about their experience of InteguSeal® but it will be noted that 16% of surgeons disagreed or strongly disagreed with the statement “I have not experienced any adverse events”. There were indeed a few reports of skin reactions following use of the product.

What issues arose in relation to implementation and adoption?

As noted above, the drying time of InteguSeal® has caused concerns with 48% of respondents disagreeing or strongly disagreeing that the drying time was satisfactory. This was of particular concern where surgeons had a large number of patients on their list, since this could mean that fewer patients could be operated on. However, some surgeons were able to make adjustments to their preparation arrangements in order to accommodate usage of the product. For example, the scrub nurse might apply InteguSeal® whilst the surgeon carried out his hand scrub. The manufacturer states that it can take between 3 and 7 minutes for the product to dry fully dependant on the environment in which it is applied.

Some problems were experienced when InteguSeal® was used in conjunction with surgical drapes, with drapes sticking to the patients' skin when the two came into contact. This may be the result of a lack of understanding of the drying times involved, which could be resolved by further training. 90% of responding surgeons agreed or strongly agreed with the statement “I have not experienced compatibility issues with other materials or techniques” which would suggest that these were isolated incidents.

Advice and tools for trusts considering introducing InteguSeal[®]

Important points to consider

Potential adopting trusts may wish to target the product initially at cardiac, obstetrics and gynaecology, general, and orthopaedic surgeons as they represented 71% of the respondent surgeons who embraced the product during the course of this evaluation.

When InteguSeal[®] is introduced, representatives from Kimberly Clark, or people involved in the introduction of the product, need to be in regular attendance in theatre to maximise adoption of the product. Product awareness should concentrate on placement of the technology, or literature to promote it, in places where it will remind staff to incorporate it in the surgical process.

“Word of mouth” between surgeons was seen to lead to an increase in uptake of the product throughout the trial. Following initial introduction, it may be advantageous to arrange for surgeons who are using the product to share their experience with colleagues.

Pre-operative procedures may need to be amended slightly to take into account the extra drying time. Additional training may be useful to ensure awareness of drying time is high and to help advise on solutions. Trusts should be clear in advance of introducing the product which staff members will be applying the InteguSeal[®] solution, as this is unlikely always to be the consultant surgeon.

Adopting trusts may also need consider how to advise patients prior to their surgical procedure about the proposed use of InteguSeal[®] in order to make them aware of potential skin reactions to the product and inform them that the product is intended to flake from the skin following completion of the surgery, thus avoiding unnecessary distress during the post surgery period.

Costs and Benefits

InteguSeal[®] would be an addition to the process of preparing patients for surgery and would therefore constitute an additional cost. The product is available through the NHS Supply Chain Catalogue. As of 25 May 2010, the price was £330.48 for 20 for the smaller size and £479.31 for 20 for the larger size equivalent to unit costs of £16.52 for the smaller size and £23.97 for the larger size. Each avoidable SSI infection is estimated to cost the NHS upto £6103, so the product would be cost effective if one infection was prevented in around 300 operations for the smaller size and 200 operations for the larger size.

Drawing up a Business Case

Trusts may wish to adopt and adapt the following model when drawing up a business case for this product. Text in italics (other than the section headings) gives information about how to complete the business case. Text in ordinary font (and the section headings) is intended to be suitable for cutting and pasting into the business case. The symbol ♥ indicates where numbers need to be inserted.

The Problem

Surgical site infection (SSI) is one of the most common postoperative complications. *Insert information about SSIs in the trust, including numbers and estimated length of additional hospital stay. If this information is not available for your trust, you could say that the prevalence of SSIs has been reported to range from 1.3 to 12.8%.^{10, 11, 12, 13}*

For most SSIs, the source of the invading pathogen is the patient's skin.¹⁴ Consequently, pre-operative skin preparation is intended to render the skin as free as possible from endogenous bacteria that may enter the surgical wound. Although skin disinfection prior to surgery drastically reduces the number of bacteria on the skin's surface, re-colonisation with bacteria from deeper skin layers and hair follicles may occur during the operation¹⁵ Regulations made under the Health and Social Care Act 2008¹⁶ require trusts to ensure as far as possible that patients are protected against identifiable risks of acquiring healthcare associated infections.

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InteguSeal[®] is recommended by the Rapid Review Panel (which assesses new and novel equipment, materials and other products that may be of value to the NHS in improving hospital infection control and reducing healthcare associated infections) as being a product where basic research and development, validation and recent in use evaluations have shown benefits that should be available to NHS bodies to include as appropriate in their cleaning, hygiene or infection control protocols.

A recent evaluation by Showcase Hospitals as part of the Department of Health's Healthcare Associated Infections Technology Innovation Programme showed that InteguSeal[®] was favourably received by surgeons.

Current Practice

Describe current practice in your trust for the prevention of SSIs.

Options

We have looked at a range of options.

You will need to decide precisely what options to include. The following are suggestions. Option 1 should always be included, as this is the baseline option against which other options will need to be compared.

1. Continue with current practice.
2. Use InteguSeal[®] for operations where there is a high risk of infection or where any infection could have particularly serious consequences. *Give examples.*
3. Use InteguSeal[®] for all operations.

Costs and Benefits

The use of InteguSeal[®] would be an addition to current practice (Option 1) and therefore would incur an additional cost, against which can be set the value of any benefits from its use.

Option 1 would therefore incur no additional cost, nor would any additional benefits accrue.

For Option 2 we estimate that InteguSeal[®] will be used in ♥ operations at an average cost of *insert figure based on current cost of large and small sizes of InteguSeal[®] and likely proportions in which each of the sizes will be used.* In the trial, the split was roughly 50:50 and this could be used as a default option. We estimate that ♥ SSIs will be avoided at a cost per case of £♥ The National Audit Office report on healthcare associated infections¹⁷ uses an estimate of £4,200 per case.

Repeat for other options.

In addition there will be transitional (and, to a lesser extent, ongoing) costs in terms of training. As with all new interventions there will be transitional costs for training

Finally, there will be some costs and benefits which are less easy to quantify.

On the cost side, the principal potential issue, particularly for operations of short duration, is the additional time involved in using InteguSeal[®] and its effect on the number of cases which can be included in a list. *Either say that changes to procedures have been identified which will deal with this problem, or say that this is a potential reason for going for an option which focuses on high risk and/or lengthy operations.*

On the benefit side, given that SSIs are associated with increased length of stay, reducing them will reduce blocked beds which may in turn help with delivery of other trust desired outcomes, such as reduced waiting times.

Conclusions and Recommendation

Taking action to reduce SSIs is desirable in order to reduce harm to patients and increase confidence in the safety of the services provided by the trust. Reducing infections also leads to benefits arising from reduced lengths of stay.

However, these benefits have to be balanced against the costs of InteguSeal[®] which are additional to current practice, and the potential effects on the number of operations which can be included in a list.

Our recommendation is *to be decided locally*

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