SUNRRISE

# Single Use Negative pRessure dressing for Reduction In Surgical site infection following Emergency laparotomy

## Site-specific Training Presentation

## PART 2

- Participant identification and Consent
- Randomisation procedures
- Intervention

UNIVERSITY OF BIRMINGHAM | BCTU Birmingham Clinical Trials Unit | WM Research Collaborative | NWRC North West Research Collaborative

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## Trial Schema: Detailed – Baseline

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**Summary of trial events and activities at baseline**

| SITE ACTIVITY | EVENT / TIME POINT | PATIENT ACTIVITY |
|---|---|---|
| | Patient admitted | |
| | Decision to operate<br>• Emergency laparotomy<br>• Primary skin closure of ≥5cm incision | |
| Given PIS<br>Contact Research Team<br>Eligibility confirmed and consent taken | | Consider participation<br>Give consent |
| Give QoL (EQ-5D & SF-12) to patient<br>Begin to complete Randomisation form | | Complete QoL (EQ-5D & SF-12) |
| | Taken to theatre | |
| Add *actual* operative details to Randomisation form<br>RANDOMISE | Skin closure commenced | |
| Apply SUNPD or Surgeon's preference of dressing (as allocated) | End of operation | |
| Complete In-Theatre form, ideally by operating surgeon<br>Add trial number to consent and QoL | Immediately post-op | |

## Patient Identification

- Potential participants will likely be identified by either a consultant or trainee surgeon once the decision to take them to theatre has been made
- Patients will be approached by a member of the research team - this member of the research team may be either a member of the clinical team or a research nurse
  - Ensure patients understand the importance of undergoing a review at day 30 when they are considering taking part
- Prior to randomisation:
  1. **Eligibility** for enrolment in SUNRRISE must be confirmed by a medically qualified doctor evidenced by signature on the randomisation form
  2. **Written informed consent** for participation in SUNRRISE must always be obtained by a doctor or nurse

**Ensure all staff involved in the trial (directly and indirectly) are aware that before a patient can be randomised, a SUNRRISE-specific consent form must be completed by the patient (or a declaration form by the personal consultee/consent from by legal representative), especially if they are new to research and/or the trial**



## Screening and screening logs

- Logs to be kept in accordance with the CONSORT guidance and GCP
- It is suggested that a research team member reviews the theatre logbook on a weekly/monthly basis to identify patients who have undergone an emergency laparotomy but were not randomised into the trial

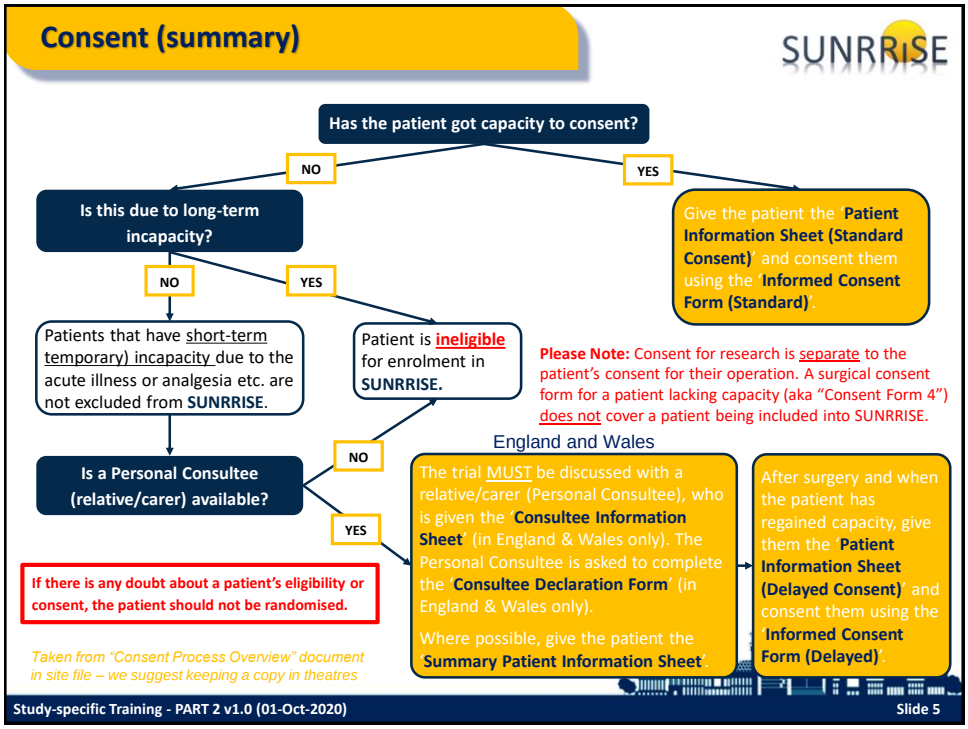
*How will this be done at your site?*

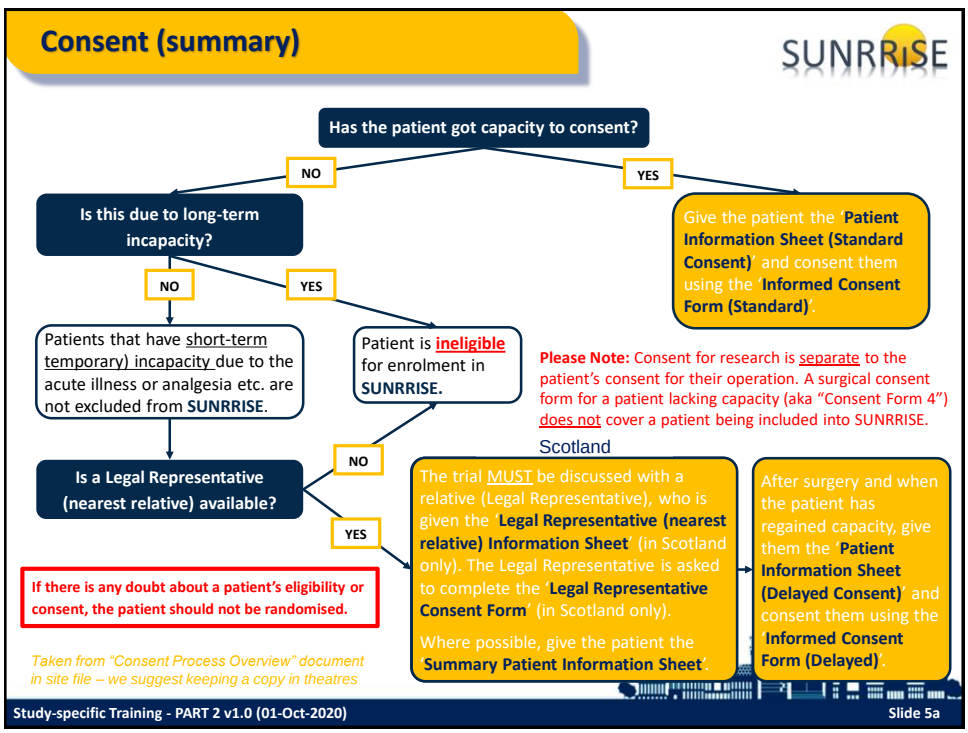
*Who will do it?*

- The reasons for non-randomisation will be recorded on the screening log
  - This information may be found by reviewing patient records or liaising with the clinical team
  - 

| *REASONS PATIENT NOT ELIGIBLE/NOT RANDOMISED* *Please use these reason codes where possible; if patient did not enter trial for any other reason please state/describe above.* | | | | | | | |
|---|---|---|---|---|---|---|---|
| A. | Procedure not an emergency laparotomy | B. | Patient aged less than 16 years old | C. | Incision of less than 5cm | D. | Skin not primarily closed |
| E. | Due to long-term incapacity, patient unable to provide informed consent | F. | Personal Consultee/legal Representative unavailable | G. | Personal Consultee/legal Representative reported objection | H. | Patient unwilling or unable to attend follow-up at 30 days post-op |
| I. | Expected return to theatre for reopening of laparotomy wound within 30 days | J. | Abdominal surgery within the preceding three months of randomisation | K. | Patient declined (please **also state reason** or confirm patient did not wish to provide one) | L. | No one GCP trained and/or assigned duty available to take consent and/or confirm eligibility |
| M. | SUNPD dressing unavailable | N. | No trained surgeon to place dressing | O. | Patient missed i.e. not identified pre-op | P. | Operation did not go ahead |

  - If patients decline, please included they reason given (or confirm that they did not wish to provide one)


Consent (summary)
SUNRRISE
Has the patient got capacity to consent?
NO
YES
Is this due to long-term incapacity?
Give the patient the 'Patient Information Sheet (Standard Consent)' and consent them using the 'Informed Consent Form (Standard)'.
NO
YES
Patients that have short-term temporary) incapacity due to the acute illness or analgesia etc. are not excluded from SUNRRISE.
Patient is ineligible for enrolment in SUNRRISE.
Please Note: Consent for research is separate to the patient's consent for their operation. A surgical consent form for a patient lacking capacity (aka "Consent Form 4") does not cover a patient being included into SUNRRISE.
England and Wales
Is a Personal Consultee (relative/carer) available?
NO
YES
The trial MUST be discussed with a relative/carer (Personal Consultee), who is given the 'Consultee Information Sheet' (in England & Wales only). The Personal Consultee is asked to complete the 'Consultee Declaration Form' (in England & Wales only).
Where possible, give the patient the 'Summary Patient Information Sheet'.
After surgery and when the patient has regained capacity, give them the 'Patient Information Sheet (Delayed Consent)' and consent them using the 'Informed Consent Form (Delayed)'.
If there is any doubt about a patient's eligibility or consent, the patient should not be randomised.
Taken from "Consent Process Overview" document in site file – we suggest keeping a copy in theatres
Study-specific Training - PART 2 v1.0 (01-Oct-2020)
Slide 5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Is this due to long-term incapacity?
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NO
YES
Patients that have short-term temporary) incapacity due to the acute illness or analgesia etc. are not excluded from SUNRRISE.
Patient is ineligible for enrolment in SUNRRISE.
Please Note: Consent for research is separate to the patient's consent for their operation. A surgical consent form for a patient lacking capacity (aka "Consent Form 4") does not cover a patient being included into SUNRRISE.
Scotland
Is a Legal Representative (nearest relative) available?
NO
YES
The trial MUST be discussed with a relative (Legal Representative), who is given the 'Legal Representative (nearest relative) Information Sheet' (in Scotland only). The Legal Representative is asked to complete the 'Legal Representative Consent Form' (in Scotland only).
Where possible, give the patient the 'Summary Patient Information Sheet'.
After surgery and when the patient has regained capacity, give them the 'Patient Information Sheet (Delayed Consent)' and consent them using the 'Informed Consent Form (Delayed)'.
If there is any doubt about a patient's eligibility or consent, the patient should not be randomised.
Taken from "Consent Process Overview" document in site file – we suggest keeping a copy in theatres
Study-specific Training - PART 2 v1.0 (01-Oct-2020)
Slide 5a

## Consent

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***Consent should only be taken after that person is informed of nature, significance, implications and risks of trial***

- Written, informed consent from a patient (or assent/declaration from a patient's personal consultee) **must** be obtained for all patients:
  - Prior to Randomisation
  - By a suitably trained, delegated investigator who is listed on the delegation log
    - *the investigator must have been trained and authorised by the PI before undertaking any study-specific activities and procedures*
  - After Patient (or consultee) Information Sheet and full verbal explanation of the trial given

If necessary, translators should be provided for patients unable to understand English



## Consent

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### Patients with capacity to give consent…

- Process for approaching the participant and taking consent occur in the usual manner
  - Patient is given the Patient Information Sheet (Standard) and the opportunity to discuss the trial with a member of the research team
  - Patient completes Informed Consent Form (Standard) and the form is countersigned by the person taking consent

**Current approved versions:**
Patient Information Sheet (Standard Consent) = **v3.0 (05-Aug-2020)**
Informed Consent Form (Standard) = **v3.0 (05-Aug-2020)**

### Patients lacking capacity *long-term*…

- If a patient's lack of capacity to consent is not temporary, they cannot be entered into the study

***i.e. ineligible for enrolment in the trial***

## Consent

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### Patients *temporarily* lacking capacity to give consent…

- In the emergency setting, patients may not have capacity to provide informed consent as a result of the condition for which they require surgery
- **IN ENGLAND & WALES** such patients can still be enrolled if they have a **Personal Consultee (PC)** present
  *Personal Consultee: a person who cares for the adult lacking capacity or is interested in that person's welfare, but is not doing so for remuneration or acting in a professional capacity*

**If a PC is unavailable, the patient cannot be entered into the study**

- Process for approach and consent:
  - Patient is given the Summary Patient Information Sheet (where possible)
  - PC is given Consultee Information Sheet and the opportunity to discuss the trial with a member of the research team
  - PC then provides assent using the Consultee Declaration Form and the form is countersigned by the person taking assent
  - Once the patient regains capacity, consent is to be sought using the Patient Information Sheet (Delayed) & Informed Consent Form (Delayed)

**Current approved versions:**
Consultee Information Sheet = **v3.0 (05-Aug-2020)**
Consultee Declaration Form = **v3.0 (05-Aug-2020)**



## Consent

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### Patients *temporarily* lacking capacity to give consent…

- In the emergency setting, patients may not have capacity to provide informed consent as a result of the condition for which they require surgery
- **IN SCOTLAND** such patients can still be enrolled if they have a **Legal Representative (nearest relative) (LR)** present
  ***Adults with Incapacity (Scotland) Act uses the hierarchy of relationships*** *- in decreasing order of closeness: Spouse; Child; Father/ Mother; Brother/Sister; Grandparent; Grandchild; Uncle/Aunt; Nephew/Niece*

**If a LR is unavailable, the patient cannot be entered into the study**

- Process for approach and consent:
  - Patient is given the Summary Patient Information Sheet (where possible)
  - LR is given Legal Representative Information Sheet and the opportunity to discuss the trial with a member of the research team
  - PC then provides consent using the Legal Representative Consnet Form and the form is countersigned by the person taking consent
  - Once the patient regains capacity, consent is to be sought using the Patient Information Sheet (Delayed) & Informed Consent Form (Delayed)

**Current approved versions:**
LR Information Sheet = **v2.0 (05-Aug-2020)**
LR Consent Form = **v2.0 (05-Aug-2020)**

## Consent

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### General points on consent…

- Investigators approaching and consenting participants must ensure they adequately explain:
  - That consent is being sought for inclusion in a randomised controlled trial
  - The trial is comparing different dressings aiming to reduce SSI rates
  - That the intervention they receive will be allocated at random
  - That participation is voluntary and the participant is free to refuse to take part and may withdraw from the trial at any time, without impact on their clinical care
  - That one additional follow-up review at 30 days post-surgery is required
  - That on discharge from hospital, they will be provided with a diary to fill out detailing interactions with healthcare professionals and an assessment of their health status
  - That the participant will be contacted at weekly intervals via telephone or text to remind them to fill out the Patient Diary
- Clinicians/nurses can introduce the trial if delegated this task (i.e. "inform patient of trial")
- Clinicians/nurses can obtain consent (or assent/declaration) - they must have been delegated this task and hold a current GCP certificate
  - There is no minimum required time between patient approach and consent



## Consent

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### General points on consent…

- Consent/Declaration forms should be check for common errors;
  - boxes not initialled, boxes missing, dates incorrect, footer missing
- What to do with the Consent/Declaration forms?
  - Original filed in ISF
  - Copy given to patient
  - Copy added to the patient's medical notes
  - Copy sent to BCTU
- Details must be documented in the patient's medical notes;
  - trial name, dates, summary of discussion, versions of documents used
- **Consent is an ongoing process** - a patient's willingness to continue should be ensured and documented in the medical notes at each FU assessment

**CHECK OUT THE GRANULE COURSE**
Available online free through the NIHR Learn (same system through which GCP training is accessed); https://learn.nihr.ac.uk/

## Patient Eligibility

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### INCLUSION CRITERIA

- ☑ **Patients undergoing emergency (non-elective) laparotomy**
- ☑ Procedures with an incision of at least 5cm
- ☑ Operations where the skin is closed primarily
- ☑ Patients aged at least 16 years
- ☑ Patients able to provide written informed consent, or consultee provide assent (declaration) if a patient temporarily lacks capacity
- ☑ Patients willing and able to undergo follow-up at 30 days post-op

### EXCLUSION CRITERIA

- ☒ Abdominal surgery within the preceding three months of randomisation
- ☒ Expected return to theatre for reopening of laparotomy wound within 30 days

**Prior to randomisation, eligibility must be confirmed by a medically qualified doctor with access to and a full understanding of the potential participant's medical history who has been appropriately delegated the duty on SUNRRISE Site Signature and Delegation Log.**



## Randomisation Procedure

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**At commencement of skin closure…**

Completed documents:
- Trial Consent (or Declaration) Form
- Baseline QoL Booklet
- Randomisation Form

24 hr automated telephone service
**0800 2802 307**
**OR**
24 hr online service
**https://w3.abdn.ac.uk/hsru/SUNRRISE**

**Take care when entering responses for the degree of contamination and stoma presence**
These are minimisation variables so if entered incorrectly it could introduce imbalances between arms – if the values entered are not accurate/do not match the Randomisation Form notify BCTU ASAP.

**Enter information**

**Trial Number issued**
_ _ _ _ _
**AND**
**Allocation given**
**SUNPD**
**or**
**Surgeon's preference**

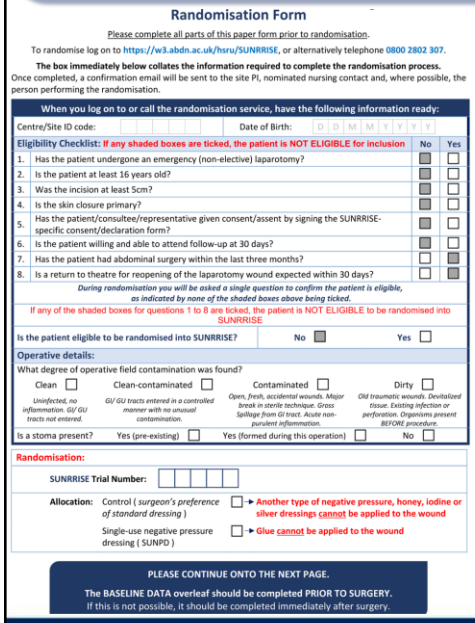
Write these on the form

**Confirmation of SUNRRISE Randomisation e-mailed to PI and nominated site contacts**
Participant details only – allocation not included to avoid unnecessary unblinding

*"Randomisation Quick Reference Guide" is provided for display in theatre and detailed instructions for the telephone service can be found in the site file (section 10)*

## Randomisation Procedure

SUNRRISE



Randomisation Form

Please complete all parts of this paper form prior to randomisation.

To randomise log on to https://w3.abdn.ac.uk/hsru/SUNRRISE, or alternatively telephone 0800 2802 307.

**The box immediately below collates the information required to complete the randomisation process.**

Once completed, a confirmation email will be sent to the site PI, nominated nursing contact and, where possible, the person performing the randomisation.

**When you log on to or call the randomisation service, have the following information ready:**

Centre/Site ID code: Date of Birth: D D M M Y Y Y Y

| Eligibility Checklist: If any shaded boxes are ticked, the patient is NOT ELIGIBLE for inclusion | | No | Yes |
|---|---|---|---|
| 1. | Has the patient undergone an emergency (non-elective) laparotomy? | ■ | ☐ |
| 2. | Is the patient at least 16 years old? | ■ | ☐ |
| 3. | Was the incision at least 5cm? | ■ | ☐ |
| 4. | Is the skin closure primary? | ■ | ☐ |
| 5. | Has the patient/consultee/representative given consent/assent by signing the SUNRRISE-specific consent/declaration form? | ■ | ☐ |
| 6. | Is the patient willing and able to attend follow-up at 30 days? | ■ | ☐ |
| 7. | Has the patient had abdominal surgery within the last three months? | ☐ | ■ |
| 8. | Is a return to theatre for reopening of the laparotomy wound expected within 30 days? | ☐ | ■ |

*During randomisation you will be asked a single question to confirm the patient is eligible, as indicated by none of the shaded boxes above being ticked.*

If any of the shaded boxes for questions 1 to 8 are ticked, the patient is NOT ELIGIBLE to be randomised into SUNRRISE

**Is the patient eligible to be randomised into SUNRRISE?** No ■ Yes ☐

**Operative details:**

What degree of operative field contamination was found?

Clean ☐ *Uninfected, no inflammation. GI/ GU tracts not entered.*

Clean-contaminated ☐ *GI/ GU tracts entered in a controlled manner with no unusual contamination.*

Contaminated ☐ *Open, fresh, accidental wounds. Major break in sterile technique. Gross Spillage from GI tract. Acute non-purulent inflammation.*

Dirty ☐ *Old traumatic wounds. Devitalized tissue. Existing infection or perforation. Organisms present BEFORE procedure.*

Is a stoma present? Yes (pre-existing) ☐ Yes (formed during this operation) ☐ No ☐

**Randomisation:**

**SUNRRISE Trial Number:** ☐☐☐☐☐

**Allocation:** Control ( *surgeon's preference of standard dressing* ) ☐ → **Another type of negative pressure, honey, iodine or silver dressings cannot be applied to the wound**

Single-use negative pressure dressing ( SUNPD ) ☐ → **Glue cannot be applied to the wound**

**PLEASE CONTINUE ONTO THE NEXT PAGE.**

**The BASELINE DATA overleaf should be completed PRIOR TO SURGERY.**
If this is not possible, it should be completed immediately after surgery.

### RANDOMISATION FORM

- **Data required to randomise** – cannot randomise if missing/unknown:
  - Patient DOB
  - Eligibility details
  - Operative details = minimisation variables
    - Take special care when entering these responses – they must be accurate
- Most parts/questions can be answered before the operation
- Some data will not be known/confirmed until the patient is in theatre

**Page 1 = information that is required to complete the randomisation process**



## Randomisation Procedure

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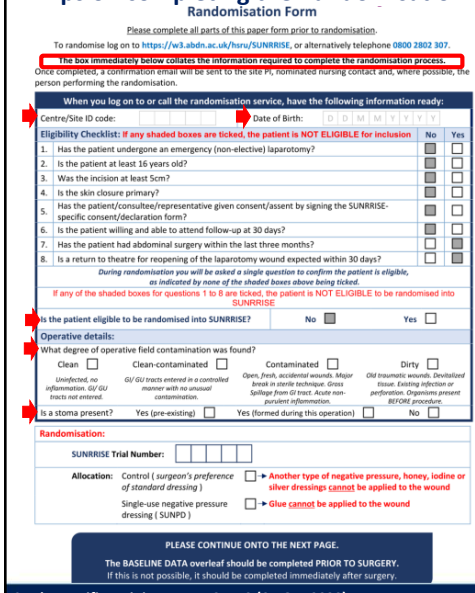
### Tips on completing the Randomisation Form…



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Centre/Site ID code: Date of Birth: D D M M Y Y Y Y

| Eligibility Checklist: If any shaded boxes are ticked, the patient is NOT ELIGIBLE for inclusion | | No | Yes |
|---|---|---|---|
| 1. | Has the patient undergone an emergency (non-elective) laparotomy? | ■ | ☐ |
| 2. | Is the patient at least 16 years old? | ■ | ☐ |
| 3. | Was the incision at least 5cm? | ■ | ☐ |
| 4. | Is the skin closure primary? | ■ | ☐ |
| 5. | Has the patient/consultee/representative given consent/assent by signing the SUNRRISE-specific consent/declaration form? | ■ | ☐ |
| 6. | Is the patient willing and able to attend follow-up at 30 days? | ■ | ☐ |
| 7. | Has the patient had abdominal surgery within the last three months? | ☐ | ■ |
| 8. | Is a return to theatre for reopening of the laparotomy wound expected within 30 days? | ☐ | ■ |

*During randomisation you will be asked a single question to confirm the patient is eligible, as indicated by none of the shaded boxes above being ticked.*

If any of the shaded boxes for questions 1 to 8 are ticked, the patient is NOT ELIGIBLE to be randomised into SUNRRISE

**Is the patient eligible to be randomised into SUNRRISE?** No ■ Yes ☐

**Operative details:**

What degree of operative field contamination was found?

Clean ☐ *Uninfected, no inflammation. GI/ GU tracts not entered.*

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Dirty ☐ *Old traumatic wounds. Devitalized tissue. Existing infection or perforation. Organisms present BEFORE procedure.*

Is a stoma present? Yes (pre-existing) ☐ Yes (formed during this operation) ☐ No ☐

**Randomisation:**

**SUNRRISE Trial Number:** ☐☐☐☐☐

**Allocation:** Control ( *surgeon's preference of standard dressing* ) ☐ → **Another type of negative pressure, honey, iodine or silver dressings cannot be applied to the wound**

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**Page 1 = information that is required to complete the randomisation process**

## Randomisation Procedure

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| Identifying Details | | | |
|---|---|---|---|
| Patient forename(s): | | Patient sex: | Male ☐ Female ☐ |
| Patient surname: | | NHS/CHI No: | |

| Confirmation of Eligibility | |
|---|---|
| **SUNRRISE eligibility must be confirmed by a medically trained individual (Doctor).** By signing this form, the named clinician confirms that the information provided on this document is true and that this patient fulfils all necessary criteria for inclusion into the SUNRRISE trial. | |
| Name of medically qualified doctor confirming eligibility for entry into the trial: | |
| Signature of medically qualified doctor confirming eligibility for entry into the trial: | |
| Date eligibility was confirmed: | D D M M Y Y Y Y |

| Quality of Life | | |
|---|---|---|
| Has the patient completed the Quality of Life questionnaires (SF-12 and EQ-5D), which should be completed prior to surgery? | No ☐ | Yes ☐ |
| ↳ If **No**, please explain why not? _____ | | |

| Baseline Data | | | |
|---|---|---|---|
| BMI: ☐☐.☐ *If BMI is not available, please provide:* | Height (in cm): ☐☐☐ | Weight (in kg): ☐☐☐ | |
| Serum albumin level (in g/L): ☐☐ | *(Expected ranged: 20-50 Max range: 5-80)* | | |
| Does the patient have known diabetes? | No ☐ | Yes ☐ | |
| ↳ If **Yes**, how is it managed: (tick all that apply) | Diet-controlled ☐ | Tablets ☐ | Insulin ☐ |
| What is the patient's smoking status? *(E-cigarette use is not considered smoking)* | Never smoked ☐ | Current smoker *(or stopped smoking ≤6 weeks ago)* ☐ | Ex-smoker *(stopped smoking >6 weeks ago)* ☐ |
| Is the patient on any immunosuppressive therapy? *(oral or inhaled immunosuppressive medication including steroids, or immunosuppressed due to pre-existing medical condition)* | No ☐ | Yes ☐ | |
| Is the patient clinically jaundiced? *(or serum bilirubin >50 µmol/L)* | No ☐ | Yes ☐ | |
| Does the patient have an active malignancy? *(does not have to be the condition being operated on)* | No ☐ | Yes ☐ | |

| Form completed by: | | | |
|---|---|---|---|
| **Full Name:** (PRINT NAME) | | **Position:** | |
| **Signature:** | | **Date:** | D D M M Y Y Y Y |

**RANDOMISATION FORM**

- Page 2 = patient identifiers, baseline data and eligibility confirmation

*Please note – Patient identifiers are only collected on the randomisation and consent forms. Other CRFs and correspondence use only Trial Number and patient initials*



## Intervention

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**PICO™ 7 is the single-use negative pressure dressing (SUNPD)**

- Kits include; 2x dressings, 8x secondary retention/fixation strips, 1x pump, 2x AA batteries, 1x belt clip, 1x instructions
- Available in 3 sizes;

| Size (cm) | 20 x 10 | 30 x 10 | 40 x 10 |
|---|---|---|---|
| Pad size (cm) | 15 x 5.6 | 25 x 5.6 | 35 x 5.6 |

- **1st dressing**
  - Applied to wound at the end of operation
  - Applied by research team member trained in application of SUNPD and delegated the duty
- **2nd dressing**
  - To be kept with patient in case dressing change is required
  - If applied, *ideally* by research team member trained of in application of SUNPD


**SUNPD supplies… Contact the Trial Office**
surrise@trials.bham.ac.uk

## Intervention

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**PICO™ 7 is the single-use negative pressure dressing (SUNPD)**

Training on the application and use of PICO 7 is provided by **Smith & Nephew** initially prior to site opening, and by the PI (or delegated individual)

*Overview (taken form Smith & Nephew PICO 7 Quick Reference Guide (PCEE2-14182-0818)…*

### Application guide

1. Clean and prepare wound according to local protocol.

**Dress**

2. Peel off the first release handle and place the dressing centrally over the wound. The port should be uppermost from the wound.
3. Remove the other two handles and smooth the dressing around the wound to prevent creasing.

**Press**

4. Insert the batteries into the device.
5. Join the device to the dressing by twisting together the tubing connectors.

6. Press the orange button to start the application of negative pressure. The green light will start to flash (indicates system working OK).

**Go**

7. Apply the fixation strips to each of the four sides of the dressing.
8. The device has a 7 day life and the dressing may be left in place for up to 7 days depending on the level of exudate.

### Dressing change indicator

**A** Dressing properly positioned and is acceptable to be left in place

**B** Dressing requires change - port may block with fluid

**C** Dressing requires change - absorbent area is full



## Intervention

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**PICO™ 7 is the single-use negative pressure dressing (SUNPD)**

Considerations when applying dressings…

- **If TAP/rectus sheath catheters are to be placed, they should be place laterally enough so they do not disrupt the seal of the dressing**
- **If wound is longer than 35cm (pad size of 40 cm dressings)…**
  - Use standard occlusive dressing for remainder of wound
  - Apply occlusive dressing first to the *lower* risk end
  - Then PICO to be placed at *higher* risk end
- **Stomas – not to be applied over stoma openings and ensure sufficient space between the stoma and wound to accommodate the adhesive rim of the dressing**
  - Fixation/secondary retention strips and adhesive rim of the dressing may be cut/trimmed to a degree BUT it must still be possible to obtain an airtight seal
  - The dressing pad should not be cut/trimmed
  - When there will be overlap with flange/wafer, applied the PICO dressing first
  - Care should be taken when changing stoma flange/wafers as they can pull at the dressing and break the seal

**If it is anticipated that a PICO 7 dressing cannot be applied, the patient should not be randomised.**

## Intervention

**PICO™ 7 is the single-use negative pressure dressing (SUNPD)**

- **Dressing to remain in place until wound review at day 7 or discharge**
  - Patients are **not** to be discharged with the SUNPD dressing
- If second dressing is unused at the end of treatment, retain with other dressing stocks
  - Can be used as additional dressings if more than 2 are needed for other SUNRRISE participants
  - Unused stock must be returned at the end of the trial
- Urgent clinical queries… contact members of the SUNRRISE TMG directly via the **"SUNRRISE Questions"** WhatsApp group;
  - access using the QR code or link given here, alternatively contact the CI, Richard Wilkin, on 07956147189 to add you to the group

https://chat.whatsapp.com/HY6np2gJPCD8dp3X4FhuFY

*The aim of the group is to allow researchers at site to communicate directly with the clinical members of the Trial Management Group about clinical queries and issues within the trial that require more immediate responses.*

**General queries should still be directed to the SUNRRISE Trial Office.**

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## Follow Up

| Time point | Activity | CRF |
|---|---|---|
| Immediately post-op | | In-theatre Form |

- **The allocation should not be recorded in the operative note/patient records**
  - State that the patient is participating in the SUNRRISE Trial and the dressing used was either SUNPD or surgeon's preference – labels/stickers are provided
- It may not be possible to prevent any mention in the patient's medical e.g. by ward staff during the patient's admission.
  - The first wound review at day 7 (or discharge if sooner) is not blinded and so is not impacted
  - The second wound review at day 30 is blinded so measures must be take to ensure the assessor is blind to the allocation – the CRF for that assessment asked the assessor to confirm they are blind.

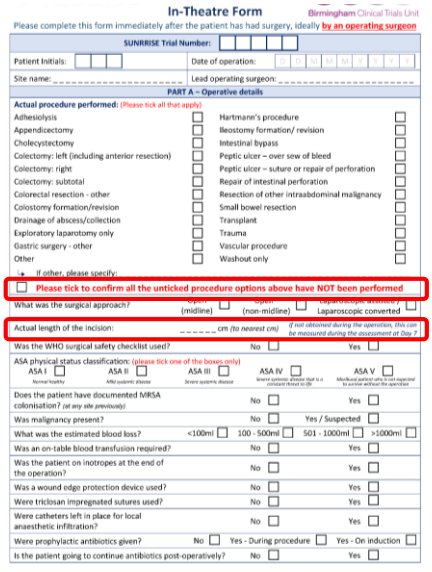
*Remember to send out the GP letter*

Study-specific Training - PART 2 v1.0 (01-Oct-2020) Slide 21

## Follow Up

SUNRRISE

### Tips on completing the In-theatre Form…


In-Theatre Form

Please complete this form immediately after the patient has had surgery, ideally by an operating surgeon

SUNRRISE Trial Number:

Patient Initials: Date of operation:

Site name: Lead operating surgeon:

PART A – Operative details

Actual procedure performed: (Please tick all that apply)

Adhesiolysis; Appendicectomy; Cholecystectomy; Colectomy: left (including anterior resection); Colectomy: right; Colectomy: subtotal; Colorectal resection - other; Colostomy formation/revision; Drainage of abscess/collection; Exploratory laparotomy only; Gastric surgery - other; Other; Hartmann's procedure; Ileostomy formation/ revision; Intestinal bypass; Peptic ulcer – over sew of bleed; Peptic ulcer – suture or repair of perforation; Repair of intestinal perforation; Resection of other intraabdominal malignancy; Small bowel resection; Transplant; Trauma; Vascular procedure; Washout only

If other, please specify:

Please tick to confirm all the unticked procedure options above have NOT been performed

What was the surgical approach? Open (midline); Open (non-midline); Open/Converted to Laparoscopic converted

Actual length of the incision: _____ cm (to nearest cm) (If not obtained during the operation, this can be measured during the assessment at Day 7)

Was the WHO surgical safety checklist used? No; Yes

ASA physical status classification: (please tick one of the boxes only)

ASA I Normal healthy; ASA II Mild systemic disease; ASA III Severe systemic disease; ASA IV Severe systemic disease that is a constant threat to life; ASA V Moribund patient who is not expected to survive without the operation

Does the patient have documented MRSA colonisation? (at any site previously) No; Yes

Was malignancy present? No; Yes / Suspected

What was the estimated blood loss? <100ml; 100 - 500ml; 501 - 1000ml; >1000ml

Was an on-table blood transfusion required? No; Yes

Was the patient on inotropes at the end of the operation? No; Yes

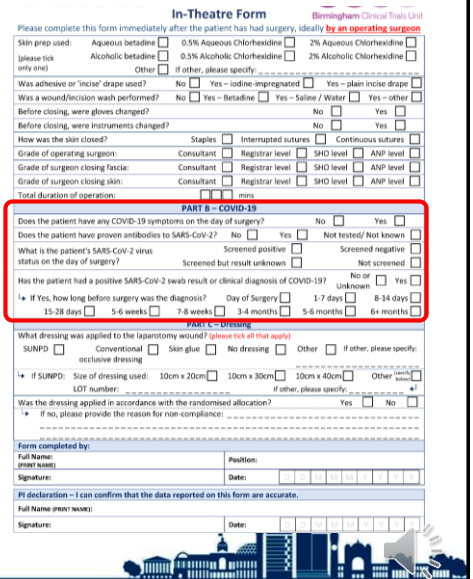
Was a wound edge protection device used? No; Yes

Were triclosan impregnated sutures used? No; Yes

Were catheters left in place for local anaesthetic infiltration? No; Yes

Were prophylactic antibiotics given? No; Yes - During procedure; Yes - On induction

Is the patient going to continue antibiotics post-operatively? No; Yes


In-Theatre Form

Please complete this form immediately after the patient has had surgery, ideally by an operating surgeon

Skin prep used: Aqueous betadine; 0.5% Aqueous Chlorhexidine; 2% Aqueous Chlorhexidine; Alcoholic betadine; 0.5% Alcoholic Chlorhexidine; 2% Alcoholic Chlorhexidine; Other (please tick only one)

If other, please specify:

Was adhesive or 'incise' drape used? No; Yes – iodine-impregnated; Yes – plain incise drape

Was a wound/incision wash performed? No; Yes – Betadine; Yes – Saline / Water; Yes – other

Before closing, were gloves changed? No; Yes

Before closing, were instruments changed? No; Yes

How was the skin closed? Staples; Interrupted sutures; Continuous sutures

Grade of operating surgeon: Consultant; Registrar level; SHO level; ANP level

Grade of surgeon closing fascia: Consultant; Registrar level; SHO level; ANP level

Grade of surgeon closing skin: Consultant; Registrar level; SHO level; ANP level

Total duration of operation: mins

PART B – COVID-19

Does the patient have any COVID-19 symptoms on the day of surgery? No; Yes

Does the patient have proven antibodies to SARS-CoV-2? No; Yes; Not tested/ Not known

What is the patient's SARS-CoV-2 virus status on the day of surgery? Screened positive; Screened negative; Screened but result unknown; Not screened

Has the patient had a positive SARS-CoV-2 swab result or clinical diagnosis of COVID-19? No or Unknown; Yes

If Yes, how long before surgery was the diagnosis? Day of Surgery; 1-7 days; 8-14 days; 15-28 days; 5-6 weeks; 7-8 weeks; 3-4 months; 5-6 months; 6+ months

PART C – Dressing

What dressing was applied to the laparotomy wound? (please tick all that apply)

SUNPD; Conventional occlusive dressing; Skin glue; No dressing; Other; If other, please specify:

If SUNPD: Size of dressing used: 10cm x 20cm; 10cm x 30cm; 10cm x 40cm; Other (specify below)

LOT number: If other, please specify:

Was the dressing applied in accordance with the randomised allocation? Yes; No

If no, please provide the reason for non-compliance:

Form completed by:

Full Name: (PRINT NAME) Position:

Signature: Date:

PI declaration – I can confirm that the data reported on this form are accurate.

Full Name (PRINT NAME):

Signature: Date:



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# Thank you

## Please remember to document your training:

- Online - using electronic SUNRRISE Training Record; https://bctu-redcap.bham.ac.uk/surveys/?s=9CXYNHDKCD
- Hardcopy – using the paper Training Log for your site, which should be located in section 3 of the Investigator Site File

## Please contact us if you have any questions…

sunrrise@trials.bham.ac.uk