

## Product Procedure Specifications Sheet

|                        |                                             |            |      |                                                                                                                                                                                                              |
|------------------------|---------------------------------------------|------------|------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Specification Sheet No | SSN-FT1357-009                              |            |      | <div>On kit</div>  <div>Off kit</div>  |
| Product Name           | 365-14524                                   |            |      |                                                                                                                                                                                                              |
| Product Description    | AV Fistula Pack                             |            |      |                                                                                                                                                                                                              |
| Range                  | 365 Healthcare                              |            |      |                                                                                                                                                                                                              |
| Manufacturer           | Shanghai ISO Medical Products Co Ltd (SIMP) |            |      |                                                                                                                                                                                                              |
| Packaging              | 120pcs                                      |            |      |                                                                                                                                                                                                              |
| Sterilisation          | EO Sterilisation                            |            |      |                                                                                                                                                                                                              |
| Issue Date             | 30 <sup>th</sup> July 2024                  | Version No | R01a |                                                                                                                                                                                                              |

|              |                                                                                                           |
|--------------|-----------------------------------------------------------------------------------------------------------|
| Intended use | Surgical Dressing Kit is intended for the out-patient service clinical use and operation wound treatment. |
|--------------|-----------------------------------------------------------------------------------------------------------|

| AV Fistula On Pack content  |               |          |                      |                                                           |
|-----------------------------|---------------|----------|----------------------|-----------------------------------------------------------|
| Item                        | Product code  | Quantity | Dimensions           | Material                                                  |
| Sterile field               | 01.08.00.0276 | 1        | 60 x 60 cm           | PE + Paper                                                |
| Nonwoven swabs              | 03.02.00.0002 | 6        | 7.5 x 7.5 cm         | 70% Rayon+30% Polyester                                   |
| Towel                       | 03.08.00.0011 | 1        | 10 x 10 cm           | Paper                                                     |
| AV Fistula Off Pack content |               |          |                      |                                                           |
| Item                        | Product code  | Quantity | Dimensions           | Material                                                  |
| Sterile field               | 01.08.00.0276 | 2        | 60 x 60 cm           | PE + Paper                                                |
| Nonwoven swabs              | 03.02.00.0002 | 5        | 7.5 x 7.5 cm         | 70% Rayon + 30% Polyester                                 |
| Island dressing             | 03.11.13.0008 | 2        | 7.2 x 5 cm           | Coated nonwoven + wound contact layer pad + release paper |
| Nonwoven balls              | 01.02.00.0040 | 4        | Diameter: Ø3cm±0.5cm | Nonwoven: 70% Rayon + 30% Polyester                       |

|                            |                                                                                                                                                                  |      |     |
|----------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|------|-----|
| Quality Certification      | ISO 13485                                                                                                                                                        |      |     |
| Device Classification      | Ila                                                                                                                                                              | Rule | N/A |
| Conformity Route           | Medical Devices Directive (93/42/EEC)                                                                                                                            |      |     |
| Storage conditions         | Store in a cool dry place away from heat and direct sunlight                                                                                                     |      |     |
| Shelf life                 | 3 Years if stored as recommended                                                                                                                                 |      |     |
| Contraindications/Warnings | No known contraindication                                                                                                                                        |      |     |
| Markings                   | 365 Healthcare, Ref, Product name, Product code, Product component list, EO Sterile, Quantity, Lot Number, Do not re-sterilize, Manufacturing date, Expiry date, |      |     |

| Document Reference | Document Name                      | Reviewed By | Approved By  | Revision Number | Issue Date                  |
|--------------------|------------------------------------|-------------|--------------|-----------------|-----------------------------|
| DMS 04-004-03      | Procedure Pack Specification Sheet | Jack Wong   | Racheal Begg | R02             | 03 <sup>rd</sup> April 2024 |



|                                                                                                                          |                                                                                                                                                                         |
|--------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                                                                                          | Latex free, Single use, EC-REP, CE Mark, Do not use if package is damaged, keep dry, keep away from sunlight, Manufacturer Name & Address, Distributor name and address |
| <b>Additional information</b>                                                                                            | Latex free and sterile. Do not use if the packaging is broken.                                                                                                          |
| <i>Medical Device and Reporting System: Incidents caused by this device must be reported immediately to our offices.</i> |                                                                                                                                                                         |

The information provided within this Specification Sheet is correct as of last revision but it is subject to change without notice.

|                                                            |                                  |
|------------------------------------------------------------|----------------------------------|
| 365 Healthcare                                             | Mediq House                      |
| T: +44 (0) 1332 413 700                                    | Arundel Avenue, Castle Donington |
| W: <a href="https://mediq.co.uk/">https://mediq.co.uk/</a> | Derby, DE74 2HJ                  |

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## Amendment Record

This procedure is reviewed to ensure its continuing relevance to the system and process that it describes. A record of contextual additions or omissions is given below. This revision history lists all changes to this document, the date of each revision, and the reason.

| Revision Number | Revision Date | Reason for Revision        | Updated by           |
|-----------------|---------------|----------------------------|----------------------|
| R01a            | 30/07/2024    | Created for Mediq UK Brand | Elizabeth Ogunkolade |
|                 |               |                            |                      |
|                 |               |                            |                      |

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