



Instructions for Use (IFU) — iCount™ Swab Docking Clip

Designed & Manufactured in Britain

Device Name: iCount™ Swab Docking Clip

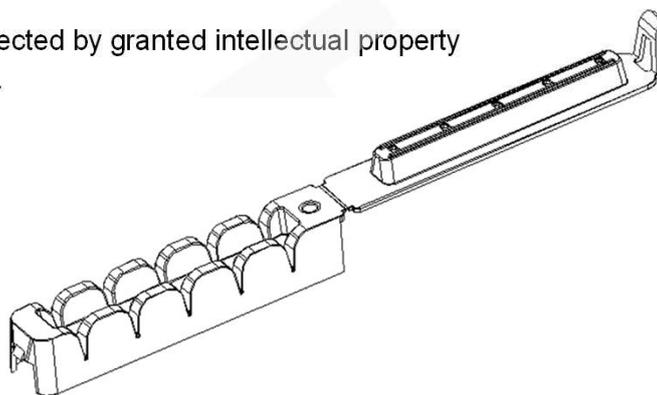
Intended Use Environment: Maternity and surgical settings (labour wards, operating theatres)

Intended Users: Midwives, obstetricians, scrub nurses, and operating theatre staff trained in swab counting procedures

Patent: The iCount™ system incorporates features protected by granted intellectual property rights and patents pending in the UK and internationally.

1. Device Description

The iCount™ clip is a single-use docking device designed to enhance safety and accuracy during surgical and childbirth swab counts. It functions as a physical checklist, allowing swab tails to be securely docked into dedicated slots, providing a clear, visual, and tactile confirmation of count completion.



2. Intended Purpose

The iCount™ Swab Docking Clip is intended to assist healthcare professionals in:

- Maintaining accurate pre- and post-procedure swab counts
- Reinforcing local Trust and WHO count policies
- Reducing the likelihood of human counting error
- Supporting traceable, safe disposal of used swabs

The iCount™ Swab Docking Clip is not classified as a medical device under current UK Medical Devices Regulations (UK MDR 2002, as amended). It is designed as a non-medical adjunct tool to support surgical and maternity teams in following existing swab count protocols. It does not come into direct patient contact and does not alter the intended purpose of any medical device or surgical consumable used during a procedure.

3. Instructions for Use

A. Pre-Procedure

1. Conduct the initial swab count in accordance with local Trust policy (two-person verification).
2. Record the count verbally; whiteboard documentation is not required when using iCount, but healthcare providers may continue to use this process
3. Keep iCount clips easily accessible on the instrument trolley or swab table.

B. Intra-Procedure

1. Any additional swab packs opened must also be counted by two staff members.
2. Dock used swabs by inserting their tails fully into each iCount slot until all five are secured.
3. Docked swabs should remain visible and not be removed during the procedure

C. Post-Procedure

1. Confirm that all swabs are docked in the iCount clip.
2. Perform a final two-person verification count.
3. Once confirmed, close the clip lid to secure all five swabs.
4. Dispose of the complete iCount clip and swabs together as per Trust infectious waste policy.

D. Transfer to Theatre (Special Circumstances)

If a patient is transferred with a vaginal swab in situ, take the iCount clip with the remaining docked swabs into theatre.

After removal of the in-situ swab, dock it into the remaining slot, perform the final two-person count, then dispose of the entire clip.

4. Warnings and Precautions

- Single use only. Do not reuse or re-sterilise.
- Do not detach swabs once docked.
- Do not use if the clip is damaged before use.
- Dispose of according to local infection control and waste policies.
- The iCount™ Swab Docking Clip is a non-medical counting aid and must be used in conjunction with standard institutional count policies. It does not replace or override those policies.

5. Storage and Handling

- Store in a clean, dry environment away from direct sunlight.
- Recommended storage temperature: 5 °C – 40 °C.
- Avoid mechanical stress or crushing before use.

6. Disposal

Dispose of the iCount clip and swabs together as clinical infectious waste, following hospital policy.

7. Additional information

Do not re-sterilise

Do not reuse

Not made with natural rubber latex

Do not use if package is damaged

Sterilised using ethylene oxide

Weight 18g

Manufactured by:

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