

Product Data Sheet & Instructions for Use



Sterilizable Irrigation & Retraction Tray
Disposable Drape, Foam, Straps, Suction Tubing Kit

SurgiServe

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I. **Descriptive Information**

Purpose of the device and indications for use

CleanField tray and disposable kit is designed for healthcare professionals to irrigate infected, contaminated & complex wounds, abscesses and open fractures. It is also ideal for vascular and micro-vascular procedures, head and neck lacerations among other procedures that involve a significant amount of irrigation and bleeding.

The tray is uniquely designed to serve as a flat working surface eliminating the need for removal until the procedure's completion. It is radiolucent and suitable for a range of medical settings such as the operating rooms, clinics, bedside or emergency rooms. It directs the fluid to the drain and allows for efficient suction during heavy irrigation ensuring a cleaner surgical field.

Additionally, the tray accommodates multiple ball-chain type hook traction for skin wound edges and retraction accessories for digits. The CleanField tray ultimately frees up the user's hands leading to a more efficient and less stressful procedure. Furthermore, its sterilizable and reusable design reduces procedural costs and biohazard waste for the healthcare system.

Description & Features of the Device

The CleanField tray is constructed from sterilizable, heavy-duty solid plastic, ensuring durability and longevity. This material has undergone rigorous biocompatibility and cytotoxicity testing, confirming its safety for extended use in open wounds.

Key features of the CleanField tray include:

- ✓ A near-flat draining basin and working surface, designed with a slope from distal to proximal, as well as a slope from side to side. This directs fluids efficiently to a single corner of the tray
- ✓ A unique corner design featuring both vertical and horizontal recesses. These recesses, positioned away from the user, facilitate fluid suction (vertical) or gravity drainage (horizontal)
- ✓ Approximate dimensions of 57x39x6cm (22.7 x 15.5 x 2.5 inches)
- ✓ Radiolucent properties and soft, rounded, contoured edges to enhance user comfort
- ✓ A rigid working surface that prevents punctures or damage from sharp instruments, wires, and drills
- ✓ A soft, contoured recess on one side (proximal aspect) to comfortably accommodate a limb or neck, preventing excessive pressure from the tray's edge
- ✓ Lightweight plastic construction for ease of handling
- ✓ Recesses along the left and right lengthwise bottom edges, designed to secure an elastic support strap at various intervals along the tray's length. This is particularly useful in procedures like wrist arthroscopy and flexor tendon repair
- ✓ Ball chain recesses around the tray's circumference, which can accommodate ball chain-type retractors for skin or finger traps for distal traction, such as in distal radius fracture cases
- ✓ Compatibility with a disposable hydrophobic foam insert. This foam serves as a padded rest, sharps container, sweep, and limb or head support.
- ✓ Integration with a sealant disposable drape at the proximal end. This feature is designed to facilitate irrigation during upper and lower limb procedures, such as elbow surgery, while also preventing fluid spillage and field contamination.

When the Device Should NOT Be Used (Contraindications)

Do not use the sterile sealant drape opening that is labelled for upper or lower limb to pass a head/neck. This can cause suffocation and death.

General Warnings and Precautions

Please note the following safety guidelines regarding the usage of this product:

Tray Edge Loading Pressure Avoid placing undue tray edge loading pressure on the extremity or neck. If the disposable foam component is not used, carefully pad the contact point between the tray and the patient to prevent temporary or permanent nerve and/or skin compression and damage.

Disposable Kit Components Do not use the table strap, limb strap, sealant tape, or dome drape labelled for upper or lower limb blue opening on the head/neck region, as it can cause suffocation and death. Do not seal around the neck region proper to avoid undue pressure on the neck vessels.

Device Lifespan After sterilizing the device for thirty (30) cycles, please ship it back to the manufacturer (Page 1 for contact information) for proper disposal.

Cracks, Breaks, Malfunction If you notice any cracks or breaks in the tray, contact customer service (Refer to Page 1 for contact information) for a replacement. Do not use the tray in such cases, as fluid leakage will contaminate the working field.

II. Operating Information

Setup & Operating Instructions for Tray and Disposable Accessories

The tray is wrapped and packaged in a padded box and shipped to the end user **non-sterile**. Upon arrival, it is **NOT** ready for immediate use. Please remove the tray from its packaging and adhere to the cleaning and drying instructions outlined below.

A-Manual Cleaning and Drying

- ❖ Always use appropriate personal protective equipment and surgical gloves during all procedures.
- ❖ Preclean with utility water: Remove excess debris, blood and other material from all surfaces paying particular attention to the corner drains. Flush the drain with utility water or use soft bristle long brush if needed, until all visible residues are removed.
- ❖ Remove any residual sticky drape remnant/residue from the tray surface and discard any disposable component except the tray itself.
- ❖ Clean the device by hand with a soft sponge avoiding abrasive pads and brushes for a minimum of 3 minutes in a solution of water and Neodisher US detergent (or equivalent neutral Ph detergent) for enzymatic cleaning at a temperature between 25°C and 32°C (or 77 °F and 90 °F).

- ❖ Rinse the tray with critical water (such as distilled, reverse osmosis RO or deionized DI) until all detergent residue is removed.
- ❖ Inspect the tray and drain recesses thoroughly for cleanliness. If necessary, repeat the cleaning steps above.
- ❖ Dry the Tray using a lint-free towel.

B-Automatic Cleaning and Drying

- ❖ Place the device in the automated washer on an incline, if possible, to facilitate drainage
- ❖ Operate the washer-disinfector cycle:

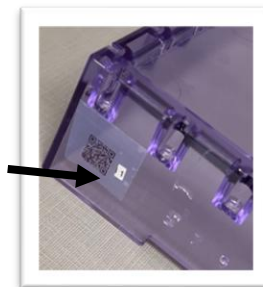
	Recirculation Time	Temperature	Detergent type
Pre-Wash	1 – 4 minutes	Cold water	N/A
Enzyme Wash (Optional)	1 – 4 minutes	43 – 50°C (110 – 122°F)	Enzymatic
Main Wash	2 – 4 minutes	43 – 82°C (110 – 180°F)	Neutral or Alkaline
Rinse 1	1 – 4 minutes	43 – 82°C (110 – 180°F)	N/A
Thermal Rinse (optional)	1 – 5 minutes	90 – 93°C (194 – 199°F)	N/A
Dry Phase	3 – 15 minutes	High (≤115°C or 239°F)	N/A

- ❖ Drain the excess water and dry with a lint free towel or pressurized air
- ❖ Visually inspect the device for cleanliness paying close attention to the drain/recess in the corner. Repeat step above in the manual or automatic clean if necessary.

C- Sterilization and Drying (AUTOCALVE ONLY)

**** THE TRAY IS NOT VALIDATED FOR STERILIZATION WITH ETHYLENE OXIDE GAS, HYDROGEN PEROXIDE BASED STERILIZERS, GAMMA OR OTHERS FORMS OF STERILIZATION ****

- ❖ Affix a provided sterilization number (solid arrow on picture below) to the tray and remove the old number from the prior cycle to keep track of the total number of cycles



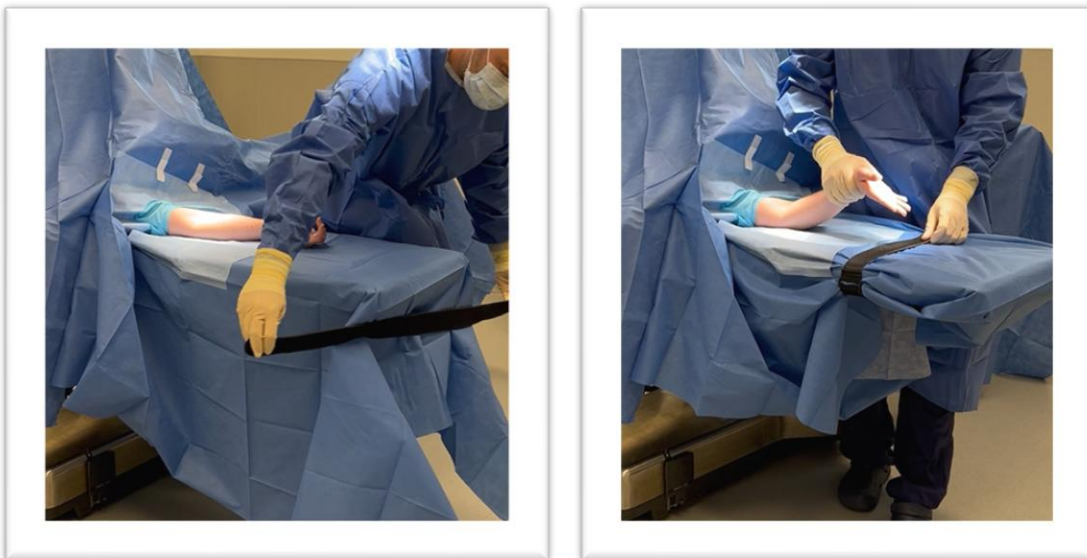
- ❖ Wrap a dual-layer sterilization wrap around the tray
- ❖ Place the tray on an open clean shelf inside the autoclave with a validated Steam Sterilization protocol: Gravity/Wrapped Cycle at Standard 121°C (250°F) for 30 minutes exposure time. Do NOT autoclave at above this recommended temperature.
- ❖ Allow the tray a drying time of 30 min and make sure the outer wrapping is dry before use. Make sure the device cools down to below 38C (100F) before use to prevent user burns.
- ❖ Store in a clean environment under the provided CleanField tag at room temperature until ready for use for a procedure.

D-Setting up the device and disposable kit for a procedure

- ❖ Unwrap the recommended disposable sterile kit. Ensure you are ordering and opening the appropriate drape for the designated procedure (head and neck vs. upper or lower limb).

STEP 1

Apply the **Table Strap** first to retract the redundant hanging surgical drape



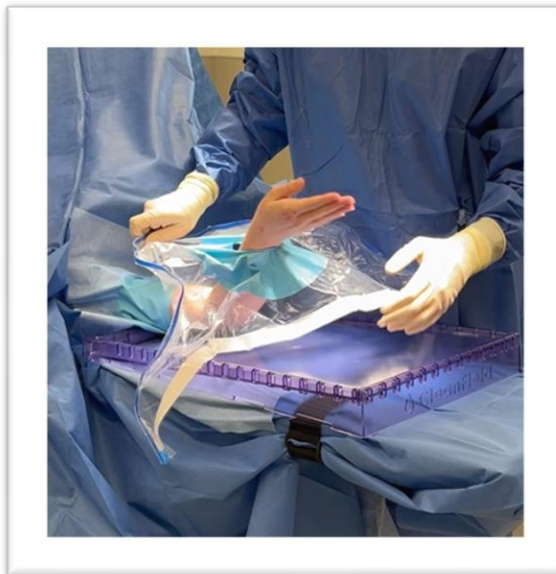
STEP 2

Place the tray on any flat working surface in the operating room, clinic or the emergency room



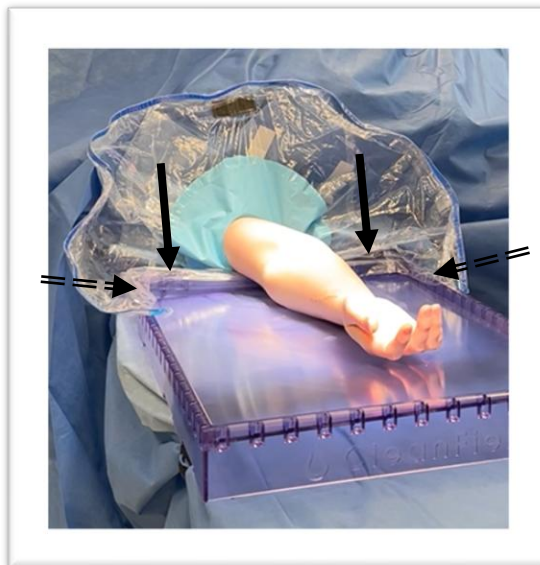
STEP 3

Place the limb on the curved/shallow side of tray and insert into blue **Dome Drape** opening



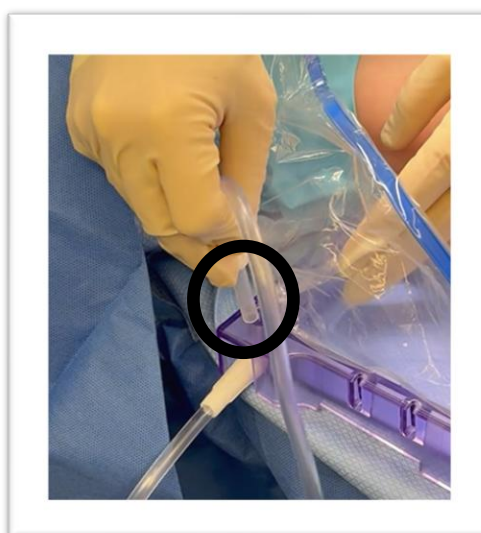
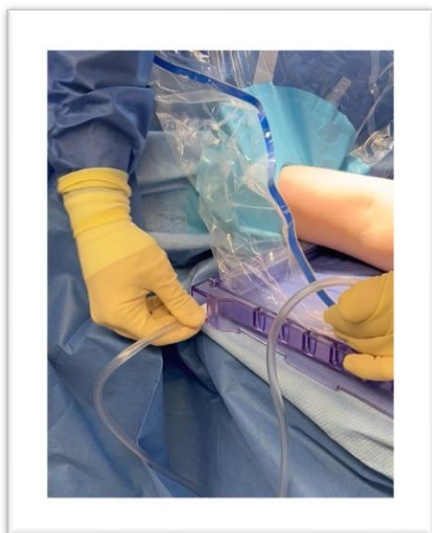
STEP 4

Peel-stick the ends of the Dome Drape on the inner walls of the proximal end of the tray. This will create an open rectangle. Stick the longer side/back wall first (solid arrow) followed by the shorter side walls (dashed arrows) second. The drape blocks fluid overflow and limits field contamination



STEP 5

Plug one suction tube onto the external horizontal drain for low volume irrigation/bleeding. Press fit (2/3 of the way down and behind the plastic dome drape) another suction tubing to the internal vertical recess for heavy volume irrigation. (Keep the Neptune plastic adaptor (black circle) attached to the 2nd tubing for optimum fit to the vertical internal recess)



STEP 6

Place the non-absorbent **Foam** component on the proximal end of the tray. It functions as a **comfortable pad** preventing direct tray edge pressure, as a **"sharps rest"** or as a **sweep** to clean the surface of the tray, or as a **positioning device**.

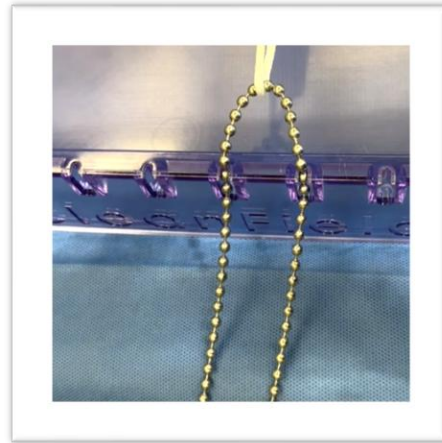


STEP 7

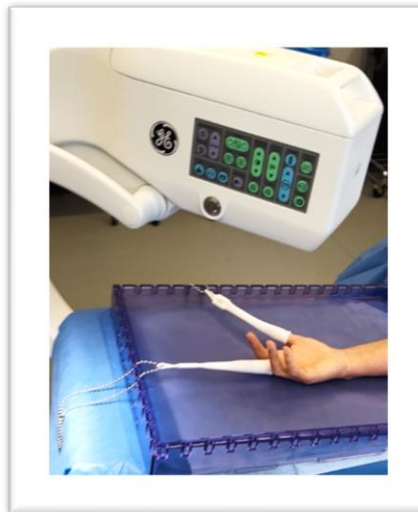
Use the **Limb Velcro Strap** to support a limb for further stability. The straps can fit underneath the tray in the side wall recesses to prevent migration (solid arrows)

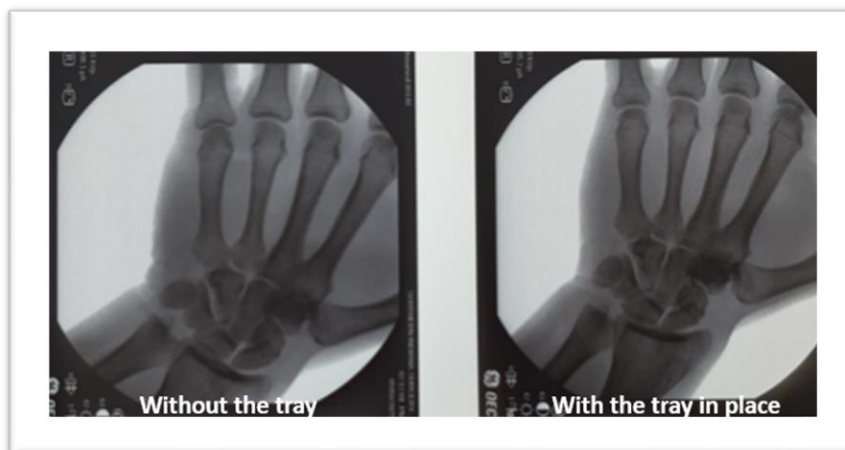


- ❖ When ready for irrigation, temporarily remove the foam from the proximal end of the tray and rest it on the opposite end of the tray to facilitate fluid drainage. Irrigate the limb or head as you would in your standard procedure. Reapply the foam to the proximal curved side when done with irrigation to function as a padded limb/head rest for the remainder of the procedure.
- ❖ Use a **ball-chain skin retractor set** (sold separately) or **finger traps** (sold separately) to retract tissues and apply finger traction as necessary to the periphery of the tray.



- ❖ The tray is designed to function as the working surface for the remainder of the procedure and does not need to be removed. You can obtain x-rays through the tray as it is **radiolucent**.





- ❖ At the end of the procedure, dispose of all single-use items components except the tray and ball chain retractors. Send the tray to the central processing and sterilization department. The tray is reusable and sterilizable.

Maintenance, Cleaning, Disposal

Please ensure that the tray undergoes debulk cleaning immediately after each use. This can be effectively done using commercially available germicidal soaps or other appropriate cleaning agents if needed. It's crucial to remove all adhered plastic material from the tray's walls and edges, as any remaining debris or stuck material can potentially clog the drain, hinder a proper seal with the suction tubing, and compromise the tray's sterility for future procedures if not completely removed.

Please discard the single-use foam, plastic drape, and straps after each procedure. To prepare the Tray and Ball-Chain retractors for the next cycle, kindly refer to the "**Cleaning and Drying**" above.

Once the tray has been wrapped and sterilized, it should be stored on a flat shelf within the clean room. Please use the provided CleanField Tag for identification until the tray is required for the subsequent procedure. The Sterilization Tracker Sheet should be hung in a visible and easily accessible location, and the number of sterilization cycles should be diligently recorded.

Please note that the tray is validated for a maximum of thirty **(30)** sterilization cycles. Upon reaching this limit, the tray must be returned to Surgi-Serve LLC for recycling and proper disposal. Please refer to page 1 for contact information to arrange the return.

III. Troubleshooting, User Assistance Information and Adverse Events

To ensure timely assistance, please report any troubleshooting issues, requests for user assistance, or adverse events immediately. When possible, please document the issue with pictures and videos. Refer to page 1 for Surgi-Serve LLC contact information.

IV. Additional Information

Clinical studies

None available as of 3.25.25

Warranty and Product Information Disclaimer

Surgi-Serve LLC /CleanField Products disclaims all warranties, whether written or oral, statutory, express, or implied, including any implied warranties of merchantability, fitness, or design. Surgi-Serve LLC or CleanField Products is not liable for any direct, incidental, or consequential loss, damages, or expense indirectly arising from the use of this product.

No representation or affirmation of fact, including statements regarding suitability for use or product performance, shall be deemed a warranty by Surgi-Serve LLC. Surgi-Serve LLC neither assumes nor authorizes any other liability or responsibility in connection with this device.

Returned Goods Authorization

Authorization for any merchandise return must be obtained in writing from Surgi-Serve LLC. Please ensure that the merchandise you are returning has not been used or sterilized. Refer to page 1 for Surgi-Serve LLC contact information.

Product Order Information

Refer to page 1 for Surgi-Serve LLC contact information.