

## Fistula Solution® Devices customer Q&A

Usage questions	Answers
Can I reuse the devices?	Devices are single use only. The devices are intended to be tailored to fit the wound bed. As the wound bed heals, it changes shape and a new device must be trimmed to best fit the wound surface. Please refer to the instructions for use.
How often do I need to change the device? What is the wear time?	Indications for the WOUND CROWN®, FISTULA FUNNEL®, and ISOLATOR STRIP® devices is to check the wound bed 24 hours after the first placement, then apply a new device within 3 days with dressing changes.
Are the Fistula Solution® Devices sterile?	Fistula Solution® Devices are not provided sterile.
How do I disinfect the Fistula Solution® Devices?	Wound cleaning protocols vary in every facility. Please follow the facility's existing protocols. Generally, the solution used to clean the patient's skin or wound can be used to rinse the devices to disinfect. After is has been swabbed or dunked in disinfecting solution, it can be rinsed in saline.  Do not autoclave.
What are the Fistula Solution® Devices made of? Do the devices contain latex?	The Fistula Solution® Devices are made of a thermoplastic elastomer. The devices are not made from natural latex rubber.

Sealing questions	Answers
How do I get a good seal between the device and the wound bed?	The devices are designed with two sealing mechanisms; a wide base flange and a bulb seal or skirt that is cut to mirror the wound bed. To assure a good seal, we also recommend applying a barrier ring to the base of the device and/or ostomy paste inside the base of the device.  See technique tips: <a href="https://fistulasolution.com/wound-crown/">https://fistulasolution.com/wound-crown/</a> <a href="https://fistulasolution.com/fistula-funnel/">https://fistulasolution.com/fistula-funnel/</a>
How do I get a good seal on the overlapping ends of the ISOLATOR STRIP®?	We recommend applying ostomy paste or a piece of barrier ring to the joint where the ends overlap.  See technique tips: <a href="https://fistulasolution.com/isolator-strip/">https://fistulasolution.com/isolator-strip/</a>
How do I get a good seal between the isolation device and the ostomy pouch?	<ol style="list-style-type: none"> <li>1. Place a barrier ring on top of the isolation device around the perimeter of the device to create a landing zone for the pouch.</li> <li>2. Use a 2-piece or window-type high-output pouch system. Cut the pouch opening over-sized, about ¼ inch larger than the opening to the Fistula Solution® Devices and place on the landing zone.</li> <li>3. Inside the pouch, place another barrier ring of the same type used for the landing zone over the seam, so half is on the base flange and the other half is on the landing zone that you just made. Seal the edge with a thin line of stoma paste. Work the stoma paste using your finger to make a solid seal.</li> </ol> See example: <a href="https://fistulasolution.com/pouch-attachment/">https://fistulasolution.com/pouch-attachment/</a>

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How do I get a good seal on uneven skin when I belt the device in place?	<ol style="list-style-type: none"> <li>1. Apply skin prep around the fistula or ostomy perimeter.</li> <li>2. Apply wedge-like pieces of a barrier ring to any skin folds or creases.</li> <li>3. Apply a thin finger swipe of stoma paste over the skin and sections of the barrier ring to form a smooth perimeter.</li> <li>4. Cut the base of the Fistula Solution® Devices to fit the perimeter.</li> <li>5. Place a belted ostomy system over the device.</li> <li>6. Place protective dressing on each side of the belt to protect skin. Have the patient lay quiet during the application process to let it all mold together. Consider placing the high-output pouch to wall suction as needed to keep pouch empty.</li> </ol>
See example: <a href="https://fistulasolution.com/belted-pouching/">https://fistulasolution.com/belted-pouching/</a>	

Application questions	Answers
Will the base of the Fistula Solution® Devices damage the wound bed?	<p>If at all concerned that the tissue may be injured:</p> <ol style="list-style-type: none"> <li>1. Cut the base of the device completely off, flush with the side flange.</li> <li>2. Attach a barrier ring to the bottom of the device.</li> <li>3. Apply a non-adherent contact layer over the wound bed, so it sits under the Fistula Solution® Devices. Cut a hole where the fistula is located.</li> </ol>
Do I cut the base of the WOUND CROWN® the same size as the fistula I am isolating?	No, cut the base completely open and create a perimeter skirt that mirrors the wound bed.
What are examples of high-output ostomy pouches?	Multiple companies make high-output pouches. Specific examples include the 19020 and 19021 from Coloplast® and the 80070 and 80110 from Hollister®.

**Note:** If the prescribed wound management plan includes 3M™ Veraflo™ Therapy, the clinician should be made aware of the warnings provided in the Instructions for Use against use of Veraflo Therapy in wounds with enteric fistula due to the potential for instillation of topical solutions into the fistula.

**Note:** Specific indications, limitations, contraindications, warnings, precautions and safety information exist for these products and therapies. Please consult a clinician and product instructions for use prior to application. Rx only.

**Note:** The WOUND CROWN®, FISTULA FUNNEL®, and ISOLATOR STRIP® are manufactured by FISTULA SOLUTION®. 3M is the exclusive distributor. Please consult a clinician and product instructions for use prior to application.



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