



March 11, 2025

Dear Valued Customer,

In our ongoing efforts to enhance the quality and service we provide to our customers, Aspen Surgical will be transitioning one of our suppliers for our Labor and Delivery products. This change is aimed at improving capacity, reducing timelines, and preventing unnecessary delays for our customers. The following changes will affect the products listed in Appendix 1.

- **Brand Change**

The Stork name and logo will be removed from all product descriptions and labels. Individual product tradenames will remain the same (e.g., Amnihook®)

- **Supplier Change**

The contract manufacturing site will be changing. Aspen will remain the legal manufacturer.

- **Sterilizer Change**

The contract sterilization site will be changing. The sterilization method will remain the same.

- **Country of Origin Change**

The country of origin for the U-Bag® will be changing from the USA to the Dominican Republic. All other products will remain the same.

Aspen Surgical confirms the safety and efficacy of these devices will be maintained through process validations conducted on any proposed changes impacting product quality.

We understand this request may have an impact on currently marketed licenses or products registrations.

If you have any questions or concerns associated with this change request, do not hesitate to contact our International Regulatory team at internationalRA@aspensurgical.com.

Thank you for your continued partnership,

A handwritten signature in black ink, appearing to read 'Marissa Hovey'.

Marissa Hovey

International Lead – Regulatory Affairs

Marissa.hovey@aspensurgical.com

Appendix 1

Part Number	Description
9210	Stork Plastibell Circumcision Device; Hospital Set; Assorted Sizes; Sterile; 1/pouch; 125 pouches/box
9211	Stork Plastibell Circumcision Device; 1.1 cm size; Sterile; 1/pouch; 125 pouches/box
9212	Stork Plastibell Circumcision Device; 1.2 cm size; Sterile; 1/pouch; 125 pouches/box
9213	Stork Plastibell Circumcision Device; 1.3 cm size; Sterile; 1/pouch; 125 pouches/box
9214	Stork Plastibell Circumcision Device; 1.4 cm size; Sterile; 1/pouch; 125 pouches/box
9215	Stork Plastibell Circumcision Device; 1.5 cm size; Sterile; 1/pouch; 125 pouches/box
9217	Stork Plastibell Circumcision Device; 1.7 cm size; Sterile; 1/pouch; 125 pouches/box
9230	Stork Plastibell Circumcision Device; Physician Office Set; Assorted Sizes; Sterile; 1/pouch; 25 pouches/box
9231	Stork Plastibell Circumcision Device; 1.1 cm size; Sterile; 1/pouch; 25 pouches/box
9232	Stork Plastibell Circumcision Device; 1.2 cm size; Sterile; 1/pouch; 25 pouches/box
9233	Stork Plastibell Circumcision Device; 1.3 cm size; Sterile; 1/pouch; 25 pouches/box
9234	Stork Plastibell Circumcision Device; 1.4 cm size; Sterile; 1/pouch; 25 pouches/box
9235	Stork Plastibell Circumcision Device; 1.5 cm size; Sterile; 1/pouch; 25 pouches/box
9237	Stork Plastibell Circumcision Device; 1.7 cm size; Sterile; 1/pouch; 25 pouches/box
9411	Stork Umbilical Cord Clamp; Yellow; Double-Grip; Non-Sterile; 250/box
9421	Stork Umbilical Cord Clamp; Yellow; Double-Grip; Non-Sterile; 2000/bag
9423	Stork Umbilical Cord Clamp; Yellow; Double-Grip; Sterile; 1/pouch; 125pouches/box
9601	Stork AmniHook; Amniotic Membrane Perforator; Yellow; Sterile; 1/pouch; 100 pouches/box
5402	Stork FootPrint Pad; Ready-Rolled; Disposable; Non-Sterile; 25/pack; 4 packs/box
7531	Stork U-Bag; Urine Collection Bag; 200mL; Pediatric; Single Specimen; Cloth Adhesive; Sterile; 1/pouch; 100 pouches/box, 4 boxes/Case
7533	Stork U-Bag; Urine Collection Bag; 200mL; Pediatric; 24 Hour Specimen; Cloth Adhesive; Sterile; 1/pouch; 50 pouches/box, 2 boxes/case
7535	Stork U-Bag; Urine Collection Bag; 100mL; Newborn; Single Specimen; Cloth Adhesive; Sterile; 1/pouch; 100 pouches/box, 4 boxes/case
7537	Stork U-Bag; Urine Collection Bag; 100mL; Newborn; 24 Hour Specimen; Cloth Adhesive; Sterile; 1/pouch; 50 pouches/box, 2 boxes/case
7540	Stork U-Bag; Urine Collection Bag; 10mL; Premie; Single Specimen; Cloth Adhesive; Sterile; 1/pouch; 100 pouches/box, 4 boxes/case