

Final Product Specification: Non-Surgical Gauze Dressing

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Rev: **1**

Effective: 12-Oct-2021

Product Description

Name	Non-surgical hemostatic gauze dressing
Synonyms	ChitoGauzeXR PRO
Description	Hemostatic dressing for the external, temporary control of severely bleeding wounds.
Gauze Composition	Polyester / rayon blend non-woven medical gauze coated with chitosan acetate and containing a radiopaque filament
Active Mixture Composition	Chitosan and Glacial Acetic Acid
Sterility	Provided sterile: gamma radiation dose limit 25 - 40 kGy, SAL 10 ⁻⁶
Sterility Manufactured By	Provided sterile: gamma radiation dose limit 25 - 40 kGy, SAL 10 ⁻⁶ Tricol Biomedical, Inc., 720 SW Washington Street, Suite 200, Portland OR 97205-3504 USA
-	Tricol Biomedical, Inc., 720 SW Washington Street, Suite 200, Portland
Manufactured By	Tricol Biomedical, Inc., 720 SW Washington Street, Suite 200, Portland OR 97205-3504 USA

Testing

Parameter	Specification
Coated gauze subassembly moisture	Lot manufactured with coated gauze subassembly certified at < 5.50% moisture
Coated gauze subassembly coat weight	0.1389 – 0.1597 g/in²
Package integrity 1) Visual inspection 2) Leak test 3) Package integrity (bubble)	 Complies to visual standard < 0.23 psi C=0



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Other Chemical and Physical Properties

Appearance	White to off white non-woven gauze
Odor	Characteristic vinegar smell
Size	3in x 4yd
X-Ray Detectable	Polypropylene Yarn filled w/ Barium Sulphate

Handling and Storage

Handling	No special handling required

Storage Store at room temperature

Transportation Information

Medical first aid supplies not otherwise classified

Disposal Considerations

No special considerations required. Observe all federal, state, and local environmental regulations.

