

## **VYCRIL PLUS SUTURA ANTIBACTERIAL**

### **DESCRIPCION**

La **SUTURA VICRYL ®PLUS ANTIBACTERIAL** (poliglactina 910) es una sutura quirúrgica sintética estéril y absorbible fabricada a partir de un copolímero compuesto en un 90% de glicolida y un 10% de L-lactida. La **SUTURA VICRYL ®PLUS ANTIBACTERIAL** está revestida con una mezcla compuesta de partes iguales de un copolímero formado por glicolida y lactida (pliglactina 370) y estearato de calcio. La sutura contiene Irgacare MP\*\* (triclosano), un agente antibacteriano de amplio espectro, en una proporción no mayor a 50µg/m. Se ha encontrado que los copolímeros en este producto no son antigénicos ni pirogénicos.

### **COMPOSICIÓN**

- Poliglactina 910
- Recubierta con copolímero, de lactida/glicolida
- Irgacere MP (triclosan)

### **ESPECIFICACIONES DE PRODUCTO TERMINADO**

PS732-003  
Version 1

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- 6.11.1. VICRYL\* Plus batches must be placed on Finished Goods Hold until all test data has been received.
- 6.11.2. Triclosan Test results will be provided to the FG department.
- 6.11.2.1. If sample results are **below the lower specifications** stated for Irgacare<sup>®</sup> MP, **reject the batch**; accept on 0 strand, reject on 1 strand out of specification.
- 6.11.2.2. If sample results are **above the upper specifications**, either average or individual, stated for Irgacare<sup>®</sup> MP, the batches must receive **Hot Room Re-work**; accept on 0 strand, reject on 1 strand out of specification.
- 6.11.2.3. Repeat the Hot Room Re-work and Triclosan Sampling step stated above until Triclosan Levels are reduced below the Upper Limit (as stated in Section 5.7.1 of this specification) or the maximum Hot Room time of 20 days (480 hours) has elapsed.
- 6.11.2.3.1. If the Triclosan Levels have not been reduced within the **maximum 20-day limit** allowable (set by PS251-017), **reject the batch**.
- 6.11.3. All Finished Goods Requirements (FG732-005) must be met prior to batch release.
- 6.12. VICRYL\* Plus will be shipped to JHCS per current VICRYL\* procedure.

### **7. REQUIREMENTS**

- 7.1. Below are additional requirements to regular **VICRYL\* specification**.

<b>Characteristic</b>	<b>Requirement Test</b>	<b>Method</b>
Triclosan Testing	Regular VICRYL* Triclosan Levels must be below 10-PPM	TM403-596
Triclosan Testing	VICRYL* Plus Triclosan Levels must meet FG732-005	TM403-593
Zone of Inhibition	Zone of Inhibition must be created	TM400-069
EtO Testing	VICRYL* Plus added to TM and must meet VICRYL* requirements	TM403-531
Moisture	VICRYL* Plus added to TM and must meet VICRYL* requirements	TM403-265

### **8. APPENDICES**

### **ALMACENAMIENTO**

El producto debe ser transportado y almacenado a temperatura ambiente, protegida de la humedad, luz solar y fuentes de calor.

