

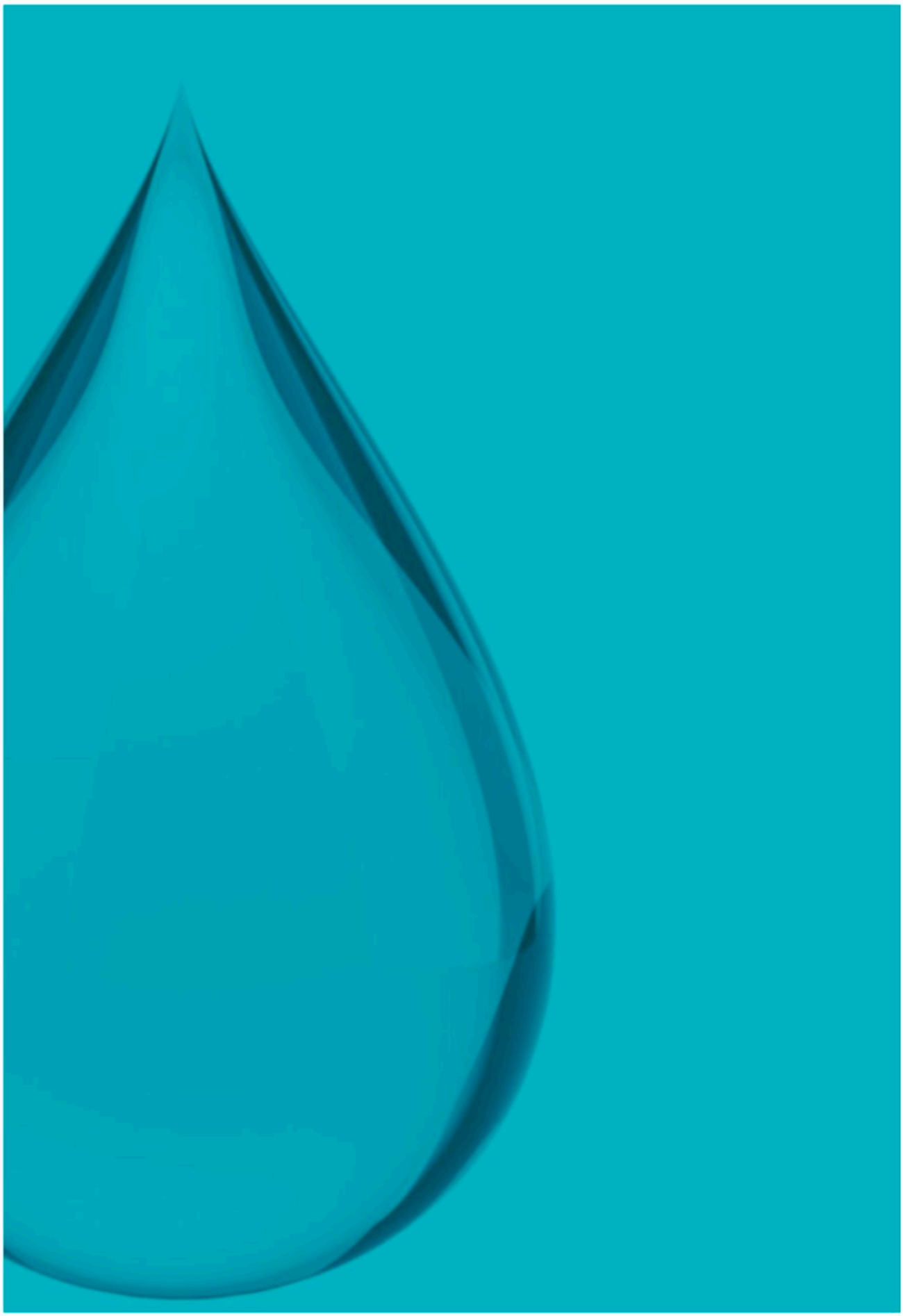
GLUBRAN®2

La potencia delicada de una gota.

—

Dispositivo médico de clase III, sintético, certificado CE para uso quirúrgico y endovascular

GEM SOLUTION COMES FROM EVOLUTION.



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6 **Información general**

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12 **Características**

14 **Biocompatibilidad**

16 **Seguridad**

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24 **Bibliografía**

ACOMPAÑANDO AL CIRUJANO, CON MEJORES RESULTADOS PARA LOS PACIENTES.

Desde hace 25 años brindando apoyo a la cirugía.

La evolución de GEM deriva del continuo compromiso con la investigación y los esfuerzos por mejorar los productos, para demostrar su eficacia y calidad, no sólo con la contribución de nuestros profesionales expertos, sino también a través de estudios clínicos sobre los dispositivos más innovadores.

CIRUGÍA GENERAL 37-84

CIRUGÍA ONCOLÓGICA
61,64,66,69,73,74,82,84-86,89,94,97

UROLOGÍA 95-105

GINECOLOGÍA 93,94,100

CIRUGÍA TORÁCICA 85-92

NEUROCIRUGÍA 20-21

ODONTOLOGÍA 22,26,27,191,193,196

OTORRINOLARINGOLOGÍA 22-28

CIRUGÍA VASCULAR
143,146, 154,162

CIRUGÍA PEDIÁTRICA 29-36, 99

CIRUGÍA CARDÍACA 12-19

ENDOSCOPIA DIGESTIVA 110-136

RADIOLOGÍA INTERVENCIONISTA

NEURORRADIOLOGÍA
3,6,77,87,110,118,121,125,134, 137-190

GLUBRAN 2





—

ADHESIVO

SELLANTE

HEMOSTÁTICO

BACTERIOSTÁTICO

ESCLEROSANTE

EMBOLIZANTE

—

UNA REVOLUCIÓN, EN UNA GOTA.

Glubran 2 para una cirugía mínimamente invasiva.

- **Versátil, que polimeriza rápidamente en contacto con los tejidos y en un ambiente húmedo.** [59,98,100,159]
- **Crea una película delgada, elástica y transpirable con una firme adhesión a los tejidos o materiales de prótesis.** [2,7,30,65,84,91]



FÓRMULA ÚNICA disponible en el mercado

Un producto de segunda generación modificado por la adición de un monómero

N-Butil 2 Cianoacrilato (NBCA) + Metacrilosisolfolano (MS)

SEIS PRODUCTOS EN UNA GOTA.

SEIS propiedades en UN SÓLO producto, para más de 80 indicaciones quirúrgicas.

ADHESIVO

Alta resistencia a la tensión: la carga mínima aceptable es 435 N [aprox 18 Kg/cm^2]. [1,2,13,16]

SELLANTE

Aplicado mediante nebulizadores específicos, forma una película delgada con propiedades de sellado e impermeabilización, gracias a su naturaleza sintética y a su alto poder adhesivo. [2,27,30,64-68,77,88,91,106-108]

HEMOSTÁTICO

Reacciona con la sangre, incluso cuando no está coagulada, induciendo una hemostasis "mecánica" en el lugar de la hemorragia. [7,62,63,95-97-116-119,121-127,131-134]

BACTERIOSTÁTICO

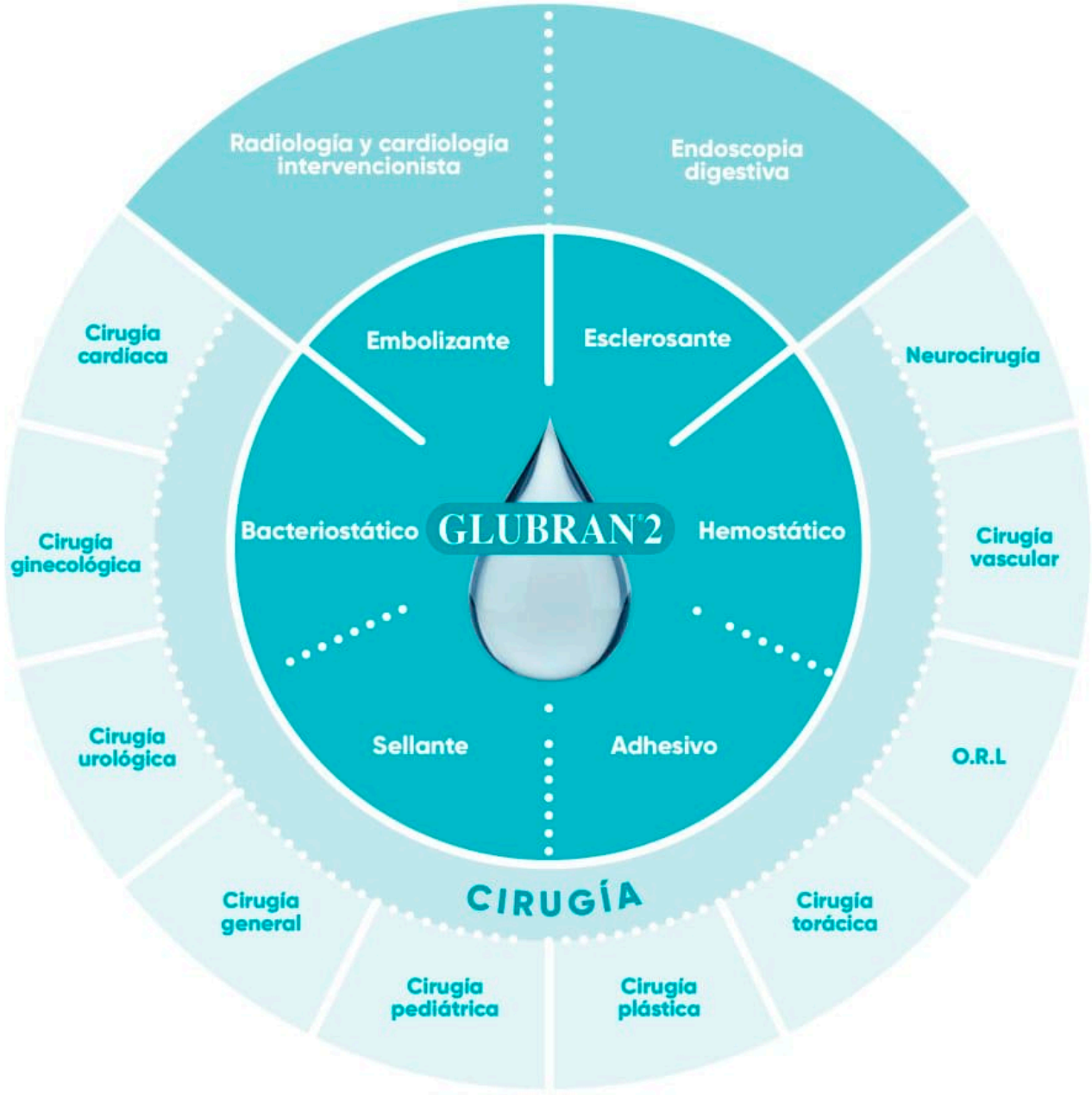
Inhibe la proliferación bacteriana durante un promedio de 7 días. [1,5,7,10,11,28, 34,76,115]

ESCLEROSANTE

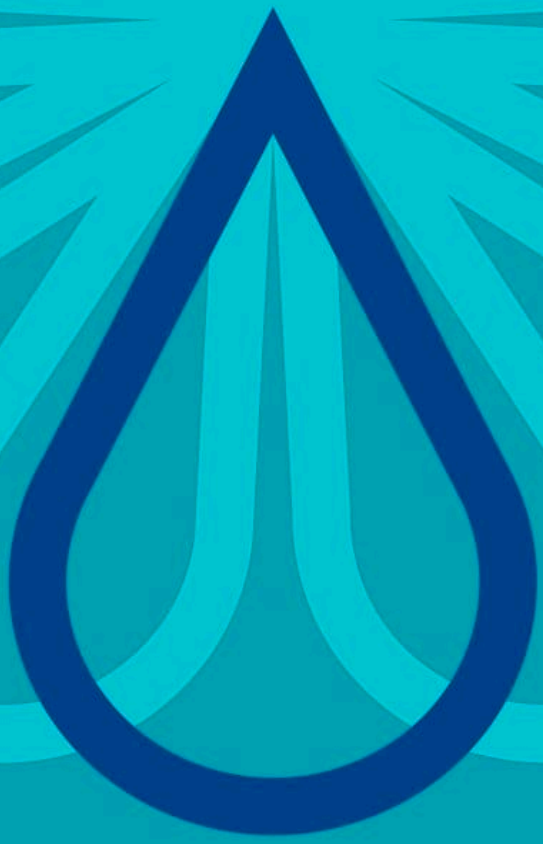
Al inyectarse en la luz de la variz o vaso sanguíneo, polimeriza, generando una trombosis a nivel local y la subsiguiente fibrosis y esclerosis. [5,113,128-132,135]

AGENTE LÍQUIDO EMBOLIZANTE

Al inyectarse en el vaso sanguíneo, se polimeriza, formando un molde adherido a las paredes del vaso, bloqueándolo. Esto genera una oclusión definitiva, equivalente a una ligadura quirúrgica. [3,6,77,87,110,118,121,125,134,137-190]


Radiología y cardiología intervencionista
Endoscopia digestiva
Embolizante
Esclerosante
Bacteriostático
GLUBRAN 2
Hemostático
Sellante
Adhesivo
Cirugía cardíaca
Neurocirugía
Cirugía ginecológica
Cirugía vascular
Cirugía urológica
O.R.L
Cirugía general
Cirugía torácica
Cirugía pediátrica
Cirugía plástica
CIRUGÍA

Cuando marca la diferencia.



GLUBRAN 2

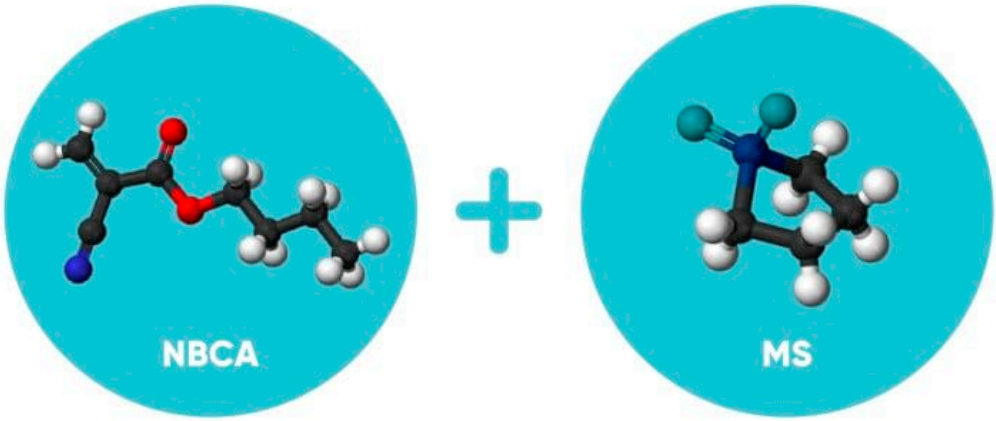
UN VERDADERO ADHESIVO Y EXCELENTE SELLANTE BACTERIOSTÁTICO.*

- **Interactúa y reacciona incluso con líquidos que no sean sangre: suero, linfa, jugos gástricos, pancreáticos, bilis, saliva, orina.**
- **Reacciona con la sangre, incluso cuando no está coagulada, induciendo una hemostasis "mecánica" en el lugar de la hemorragia.** [63-84,95,98-109,197]
- **La hemostasis siempre está garantizada, incluso en pacientes anticoagulados o en pacientes con coagulopatías hereditarias.** [103,143,146,161]

*1,2,5,7,10, 11,13,27,28,30,34,64-68,77,88,91,106-108,192

GLUBRAN 2 / CARACTERÍSTICAS QUÍMICO-FÍSICAS

UNA BIOQUÍMICA SEGURA.



Apariencia

TRANSPARENTE

Olor

TÍPICO DE LOS CIANOACRILATOS

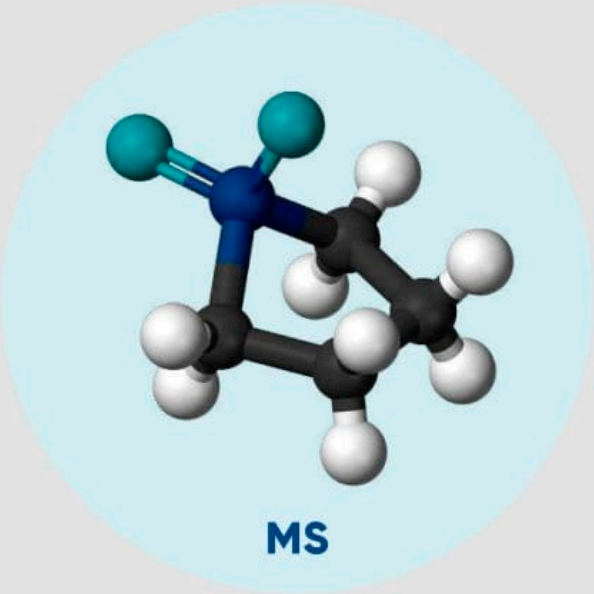
Densidad

SIMILAR AL AGUA [1]

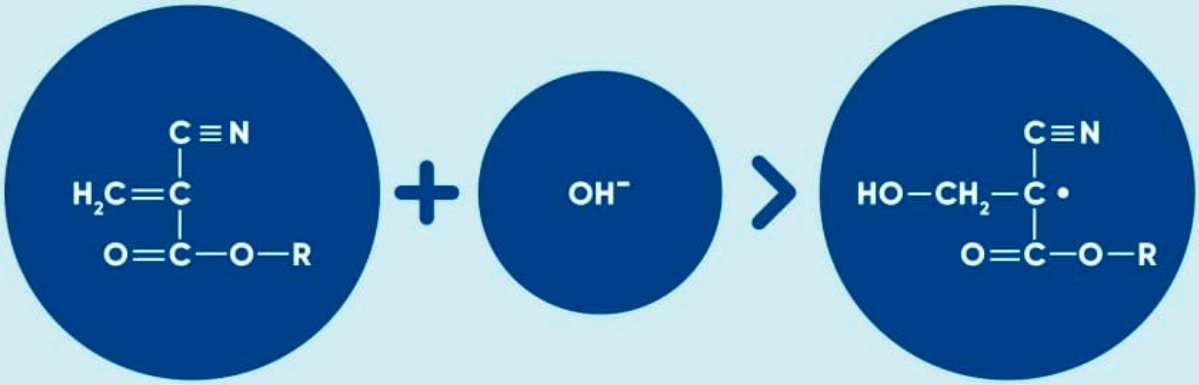
- **Listo para usar** [1,7,35,37,196]
- **NO polimeriza en presencia de aire** [142]
- **Almacenamiento entre +2 y +8 ºC**
- **Puede permanecer a temperatura ambiente (22,5+/-2,5 ºC) durante 5 días** [1]
- **Eficaz en un ambiente húmedo** [1,59,98,100,159]

Las ventajas del MS:

- Temperatura de polimerización: 45 ºC, muy por debajo de los 80-90 ºC típicos de los cianoacrilatos monoméricos puros. [6,8,59, 98,100,159]
- Biocompatibilidad. [1,2,5,7,200]
- NO hay necrosis de tejidos. [3,7,6,172]
- Elasticidad de la película al final de la polimerización. [2,7,30,65,84,91]



POLIMERIZACIÓN [192,194,198]



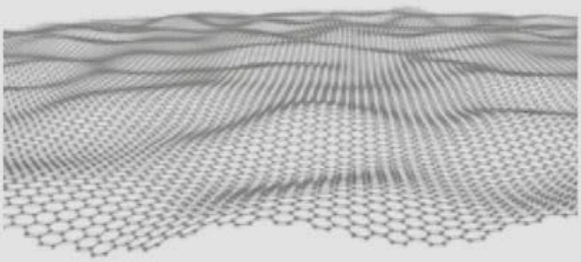
MONÓMERO

los iones desencadenan la polimerización

monómero intermedio inestable

En:

- **Entornos húmedos y tejidos**
- **SANGRE u OTROS LÍQUIDOS CORPORALES (suero, linfa, jugos gástricos, pancreáticos, bilis, saliva, orina).**
- **Polimeriza después de 1-2 segundos y termina después de 60-90 segundos.**



- Durante la polimerización se forma una película delgada y elástica que se adapta a la anatomía de los tejidos. [106-108]
- Al final de la polimerización, la superficie de la película ya no es adhesiva. [8]

NOTA

El agua destilada/glucosa/manitol no activan la polimerización. [3,7,6,172]


Sin residuos,
sin dejar
rastros.

GLUBRAN 2

UNA PELÍCULA BIODEGRADABLE.

DEGRADACIÓN HIDROLÍTICA

Las carboxilesterasas que circulan en la sangre BIODEGRADAN.

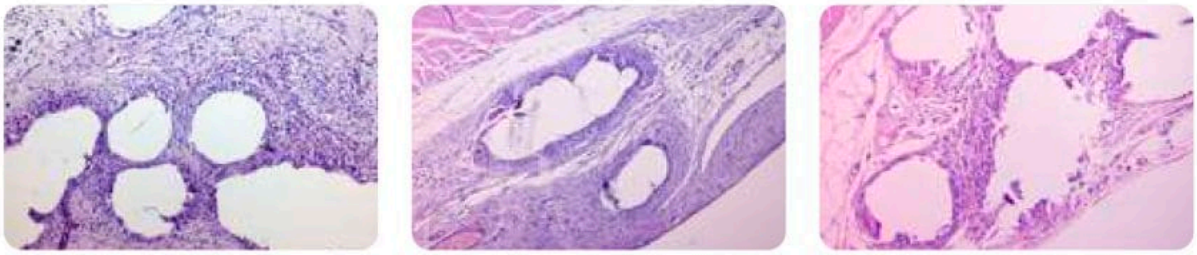
Glubran®2 a través de mecanismos hidrolíticos, en un periodo que va de 15 días a 6 meses.

Los productos de la degradación se eliminan del cuerpo a través de los riñones y los pulmones. [65]

En los tejidos más vascularizados, la eliminación es más rápida. [55,200]

Glubran®2 no detiene el proceso de curación y regeneración de los tejidos.

Las mismas células de tejido recién formadas penetran en la película de Glubran®2 y continúan colonizándola, al reproducirse, hasta que la eliminan. [55,200]



7 DÍAS | **15 DÍAS** | **30 DÍAS**

Muestras histológicas de secciones transversales de la pared abdominal de ratas sometidas a una intervención de reparación de hernia con fijación de prótesis realizada con Glubran®2. Interacción entre las fibras de la red de prótesis y los tejidos huésped a los 7, 15 y 30 días después de la cirugía (Modificado por Poli et Al. 2019). [200]

UNA GOTA DE SEGURIDAD.*

PRUEBA DE BIOCOMPATIBILIDAD[1]

- Citotoxicidad
- Genotoxicidad
- Mutagenicidad

PRUEBAS EN TEJIDOS[1]

- Reactividad intracutánea en conejos
- Sensibilización alérgica en cobayas
- Prueba de implantación muscular en conejos

RESULTADOS

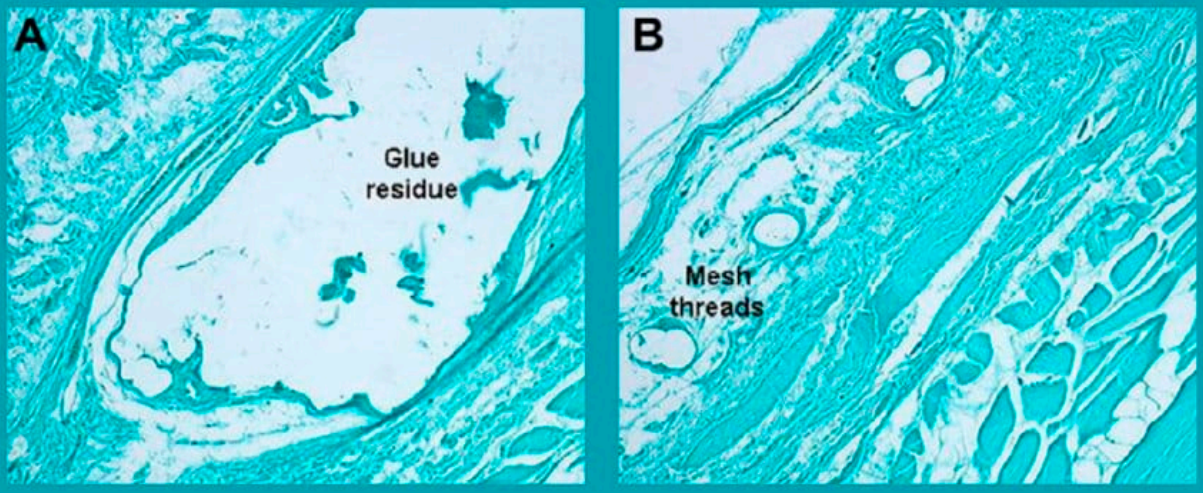
El producto causa una inflamación moderada, típica de las reacciones a cuerpos extraños como los hilos de sutura [1,7,200]

NINGUNA inflamación crónica [1,3,6,7,200]

Una vez finalizada la polimerización, Glubran® 2 se comporta como un BIOMATERIAL INERTE [1,2,7,27,78,202]

- Más de 2 millones de tratamientos
- 25 años de experiencia
- Más de 200 publicaciones

*52,161,166,192,194,201



"Pegamento quirúrgico a base de cianocrilato como alternativa a los puntos de sutura para fijar las redes en la reparación de la hernia. " [7]

- **... No se observaron PMN (PoliMorfoNucleares), células necróticas o células apoptóticas.**
- *"...cuando finalmente se sintetizaron los cianoacrilatos con cadenas alquílicas más largas (degradación más larga), éstos comenzaron a utilizarse clínicamente sin histotoxicidad..."* [192]

Soluciones en constante evolución.



> G-NB-2



> G-NB-50



> G-NB2S-25

1 ml / 0.5 ml / 0.25 ml

10 monodosis estériles en blíster de aluminio

Periodo de validez de 2 años



APLICACIONES PERSONALIZADAS.

Amplia gama de aplicadores dedicados.

Dispositivos para aplicaciones gota a gota



G2-DCD-210-8T



G-LLS

Punta para la aplicación lineal delgada



G-DT

Catéteres laparoscópicos para aplicación gota a gota



G2-LPC

G2-LPC-RIG

Nebulizadores para:

Laparoscopia



G2-NBT



G2-NBT-SMALL



G2-NBT RIG

Laparotomia



G2-NBT-SHORT

G2-NBT SM SHORT

GLUTACK

Dispositivo de fijación laparoscópica atraumática de prótesis de hernia



GB-DS-30
GB-DS-60

GB-DS SH 30
GB-DS SH 60

COMO SELLANTE BACTERIOSTÁTICO

CIRUGÍA GENERAL

Para evitar y reducir

Micropérdidas y desbordamientos de liquidos con la consiguiente formación de fistulas, seromas y linforrea.

Para sellar

- Anastomosis (vasculares, gastrointestinales, biliares, urológicas) [2,5,7,29,192,194]
- Suturas [7,9,19,26,28,43,47,66,85]
- Lineas de resección manuales y mecánicas [15,63-66,82,106]
- Superficies de resección de parénquimas y órganos (higado, riñones, páncreas, bazo, pulmones) [69,70,81,82,85,86,91,95,97,192]
- Cavidades quirúrgicas después de la extirpación de órganos o masas tumorales [74,84,94,97]

Para tratar

- Fistulas (biliares, anales, perianales, urinarias, faringeas, de liquido cefalorraquideo, bronquiales, pleurales, esofágicas, traqueoesofágicas, gástricas, gastrointestinales, duodenales y pancreáticas) [22,32,75-80,88,90,92,99,110-115]

CIRUGÍA DE HÍGADO

Para prevenir

La formación de bilomas y "fugas" biliares después de intervenciones de cirugia de higado y colecistectomia [81,82,152,159]

CIRUGÍA TORÁCICA

Para hacer aerostasis

Intervenciones de resección pulmonar, lobectomias, neumonectomias, bullectomias, reducciones de volumen, resecciones traqueobronquiales [85-92]

NEUROCIRUGÍA

Para sellar

- Suturas de plásticos durales craneales y espinales en combinación con otros productos (gasas, esponjas hemostáticas) [20]
- El acceso transesfenoidal de la silla turca, para la extirpación de adenomas hipofisarios [21]

CIRUGÍA DE MAMA Y GINECOLÓGICA

Para cerrar y sellar

- Vasos linfáticos seccionados, para prevenir y reducir la formación de seromas y linforrea [84,94]

COMO ADHESIVO

CIRUGÍA

Para fijar

- Prótesis de hernia [4,7,9,37-60,93]
- Prótesis en la sacrocolpopexia [93]
- En la cirugia plástica vaginal, perineal, uterina [24-25]
- Omento [106-108,204]
- Parche de tejido (biológico y sintético) [6,12-14,27,61,105]

Para reemplazar las suturas en

- Reparación de pequeñas laceraciones epicárdicas [14-16,208]
- Timpanoplastia [24,25]
- Uvuloplastia [28]
- Circuncisión, fimosis y frenulotomia [33-35,103]
- Cierre de los puntos de inserción de los trócares
- Heridas quirúrgicas [10,11,26,47,192,207,20]
- Cirugia dental [22,26,27,193]

Para pegar

- Tejidos dañados [17,27, 205,206]
- Fragmentos de hueso y óseo-cartilaginosos [207]
- Válvulas fonatorias traqueoesofágicas

Para ocluir

- Fistulas
- Conductos (biliares, pancreáticos, etc.)
- Canales (linfáticos, etc.) [22,32,75-80,88,90,92,99,110,115]

COMO HEMOSTÁTICO

PARA TODOS LOS TIPOS DE INTERVENCIONES QUIRÚRGICAS

- Bloquea las hemorragias en forma de goteo
- Se adhiere firmemente a los sitios hemorrágicos
- Se adapta a los micropliegues de los tejidos

Una solución simple y efectiva para lograr una hemostasis rápida en [7,62,63,95-97-116-119,121-127,131-134]

- Lesiones con hemorragia en forma de goteo después de una cirugia oncológica con extracción parcial o total de un órgano
- Superficies de resección de diversos órganos (higado, riñones, bazo, páncreas, pulmones)
- Anastomosis vasculares y cardiacas (bypass arterial y venoso, fistulas arteriovenosas, prótesis vasculares, reparación de aneurismas)
- Superficies orofaringeas sangrantes
- Tejidos parenquimatosos en laceraciones, lesiones hemorrágicas
- Lecho del colecisto, de la vejiga
- Quistes de ovarios, miomectomias, histerectomia
- Úlceras gastroduodenales, con inyección endoscópica en la submucosa

COMO ESCLEROSANTE

Asistente de endoscopista [110-190]

Al inyectarlo dentro de las várices (esofágicas, gástricas, duodenales) polimeriza y ocluye el vaso, induciendo la esclerosis. [5,113,128-132,135]

VARIZ SANGRANTE

1. Sangrado de la variz
2. Inyección de Glubran® 2
3. **Variz ocluida**

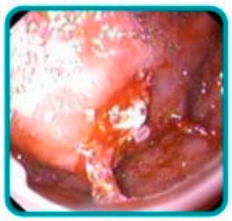
Tratamiento endoscópico de varices gástricas (Autor Prof. G. Battaglia).



1.



2.



3.

COMO AGENTE EMBOLIZANTE LÍQUIDO

Asistente de los radiólogos intervencionistas (cuerpo, cabeza y cuello)

[3,6,77,87,110,118,121,125,134, 137-190]

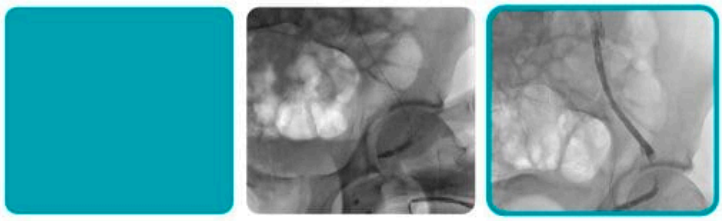
- Al inyectarse en el vaso sanguíneo, se polimeriza, formando un molde adherido a las paredes del vaso, bloqueándolo y generando una oclusión definitiva sin recanalizaciones.

VARICOCELE [142]

Pre-embolización

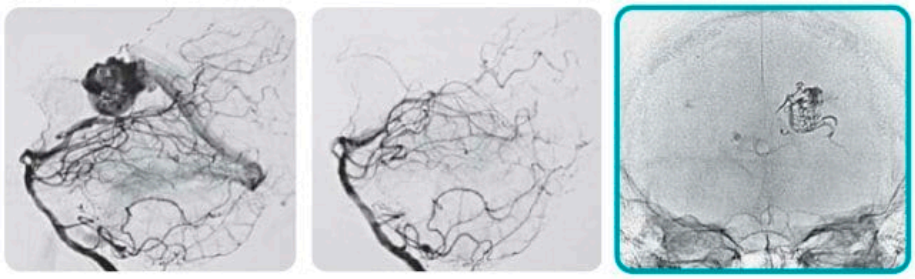
Microcateterización

Post-embolización



EMBOLIZACIÓN DE UNA MAV [142,190]

El sangrado de la MAV antes y después de la inyección de Glubran® 2 con la obtención de una **completa obliteración y resolución.**



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Cirugía cardíaca

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UNA CALIDAD CERTIFICADA.

Gracias a los esfuerzos compartidos de un equipo de profesionales en la certificación clínica y regulatoria, el sistema de calidad y el proceso de producción de GEM ha obtenido la certificación ISO 13485:2016 y ISO 9001:2015. GEM también tiene la certificación MDSAP ya que los dispositivos producidos están autorizados para su venta en Canadá, Brasil y Australia.

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