



**GLUBRAN<sup>®</sup>2**

## **La potenza delicata di una goccia.**

—  
**Dispositivo medico di classe III,  
sintetico, certificato CE per uso  
chirurgico ed endovascolare**

**GEM** SOLUTION  
COMES FROM  
EVOLUTION.



# Sommario

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**GLUBRAN 2** / INFORMAZIONI GENERALI

# A FIANCO DEL CHIRURGO, CON MIGLIORI RISULTATI PER I PAZIENTI.

**Da 25 anni a sostegno  
della chirurgia.**

L'evoluzione di GEM deriva dal continuo impegno per la ricerca e dagli sforzi per il miglioramento dei prodotti, per dimostrarne l'efficacia e la qualità, non soltanto con il contributo dei nostri esperti professionisti, ma anche attraverso studi clinici sui dispositivi più innovativi.

**CHIRURGIA GENERALE** 37-84

**CHIRURGIA ONCOLOGICA**

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

**UROLOGIA** 95-105

**GINECOLOGIA** 93,94,100

**CHIRURGIA TORACICA** 85-92

**NEUROCHIRURGIA** 20-21

**ODONTOIATRIA** 22,26,27,191,193,196

**OTORINOLARINGOIATRIA** 22-28

**CHIRURGIA VASCOLARE**

143,146, 154,162

**CHIRURGIA PEDIATRICA** 29-36, 99

**CHIRURGIA CARDIACA** 12-19

**ENDOSCOPIA DIGESTIVA** 110-136

**RADIOLOGIA E NEURORADIOLOGIA  
INTERVENTISTICA**

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







—

**ADESIVO**

**SIGILLANTE**

**EMOSTATICO**

**BATTERIOSTATICO**

**SCLEROSANTE**

**EMBOLIZZANTE**

—

# UNA RIVOLUZIONE, IN UNA GOCCIA.

## Glubran 2 per una chirurgia mininvasiva.

- **Versatile, polimerizza rapidamente a contatto con i tessuti ed in ambiente umido** 59,98,100,159
- **Crea una sottile pellicola elastica e traspirante con una salda adesione ai tessuti o ai materiali protesici** 2,7,30,65,84,91



**FORMULA UNICA** disponibile  
in commercio

Un prodotto di seconda  
generazione modificato per  
aggiunta di un monomero

**N-Butil 2 Cianoacrilato (NBCA)+  
Metacrilossisolfolano (MS)**

# SEI PRODOTTI IN UNA GOCCIA.

**SEI proprietà in UN SOLO prodotto,  
per oltre 80 indicazioni chirurgiche.**



## **ADESIVO**

Elevata resistenza tensile: il carico minimo accettabile è 435 N  
[circa 18 Kg/cm<sup>2</sup>] <sup>1,2,13,16</sup>



## **SIGILLANTE**

Applicato tramite gli specifici nebulizzatori, forma una pellicola sottile con  
proprietà sigillanti e impermeabili, grazie alla natura sintetica e all'elevato  
potere adesivo <sup>2,27,30,64-68,77,88,91,106-108</sup>



## **EMOSTATICO**

Reagisce con il sangue, anche quando è scoagulato, inducendo un'emostasi  
"meccanica" nel sito di sanguinamento. <sup>7,62,63,95-97-116-119,121-127,131-134</sup>



## **BATTERIOSTATICO**

Inibisce la proliferazione batterica per una media di 7 giorni. <sup>1,5,7,10,11,28, 34,76,115</sup>



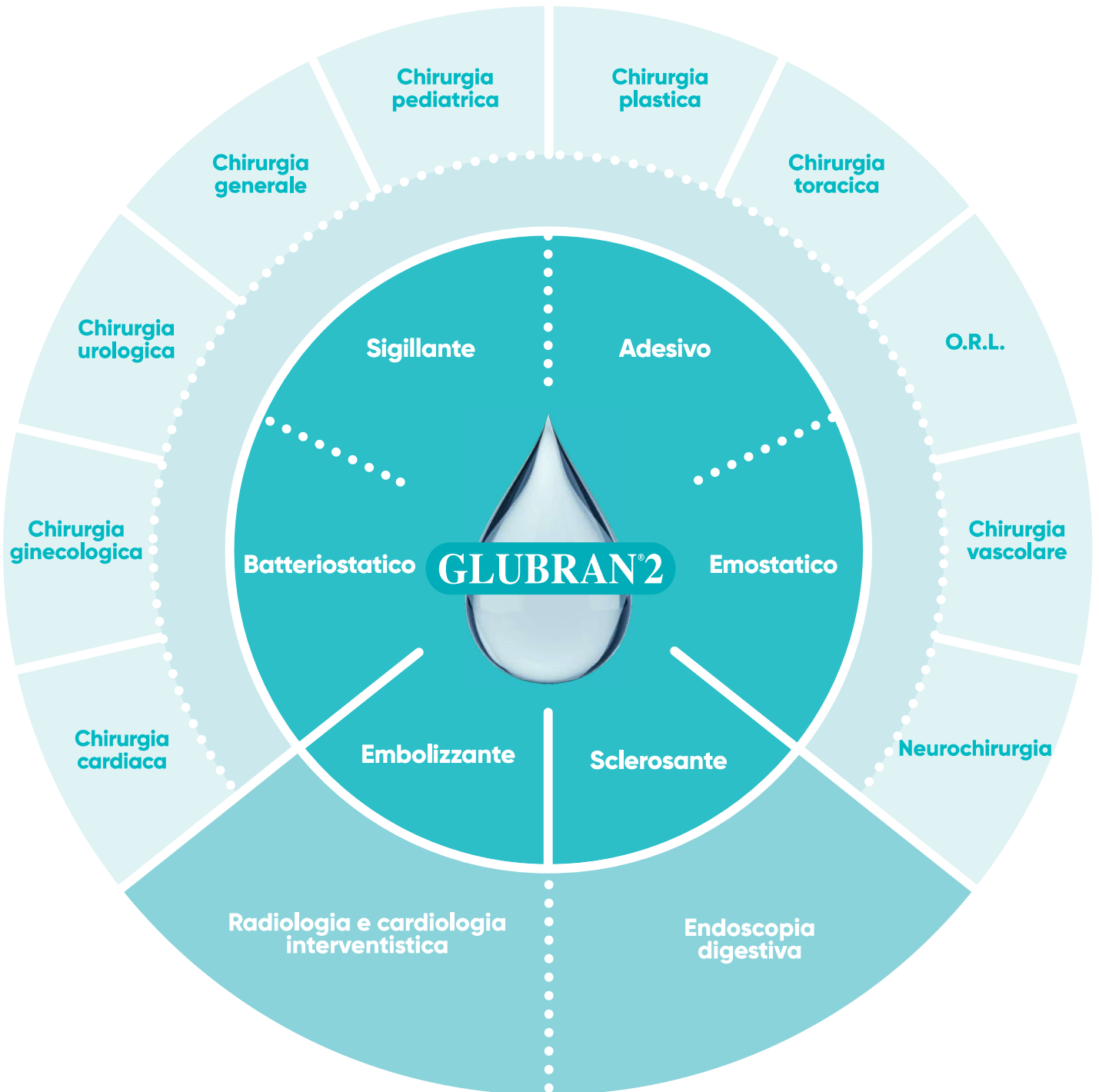
## **SCLEROSANTE**

Iniettato nel lume del vaso/varice, polimerizza generando una trombosi a livello  
locale e conseguente fibrosi e sclerosi. <sup>5,113,128-132,135</sup>



## **AGENTE LIQUIDO EMBOLIZZANTE**

Iniettato nel vaso sanguigno polimerizza, formando uno stampo aderente  
alle pareti del vaso, ostruendolo. Si genera così un'occlusione definitiva,  
equivalente alla legatura chirurgica. <sup>3,6,77,87,110,118,121,125,134,137-190</sup>



**Quando fa  
la differenza.**

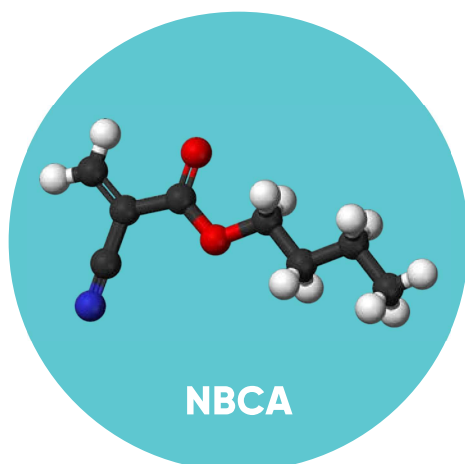


# UN VERO ADESIVO ED ECCELLENTE SIGILLANTE BATTERIOSTATICO.\*

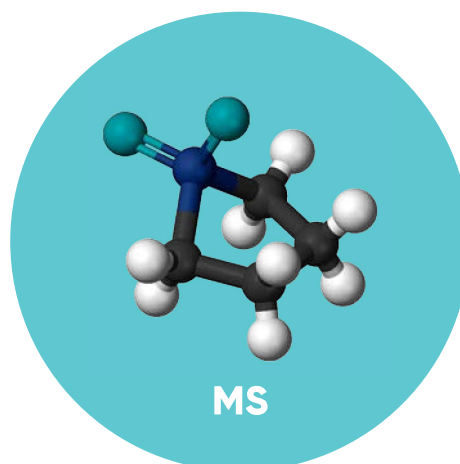
- **Interagisce e reagisce anche con liquidi diversi dal sangue: siero, linfa, succhi gastrici, pancreatici, bile, saliva, urine.**
- **Reagisce con il sangue, anche quando è scoagulato, inducendo un'emostasi "meccanica" nel sito di sanguinamento.** <sup>63-84,95,98-109,197</sup>
- **Emostasi sempre garantita, anche nei pazienti anticoagulati o nei pazienti affetti da coagulopatie ereditarie.** <sup>103,143,146,161</sup>

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

# UNA BIOCHIMICA AFFIDABILE.



+



Aspetto

**TRASPARENTE**

Odore

**TIPICO DEI  
CIANOACRILATI**

Densità

**SIMILE ALL'ACQUA <sup>1</sup>**



**Pronto all'uso** <sup>1,7,35,37,196</sup>



**NON polimerizza in presenza di aria** <sup>142</sup>



**Conservazione tra +2 e +8 °C**



**Può restare a temperatura ambiente  
(22,5+/-2,5 °C) per 48 ore <sup>1</sup>**



**Efficace in ambiente umido** <sup>1,59,98,100,159</sup>

I vantaggi dell'MS:



Temperatura di polimerizzazione:  
45 °C, molto inferiore agli 80-90 °C  
tipici dei cianoacrilati monomerici  
puri. <sup>6,8,59, 98,100,159</sup>



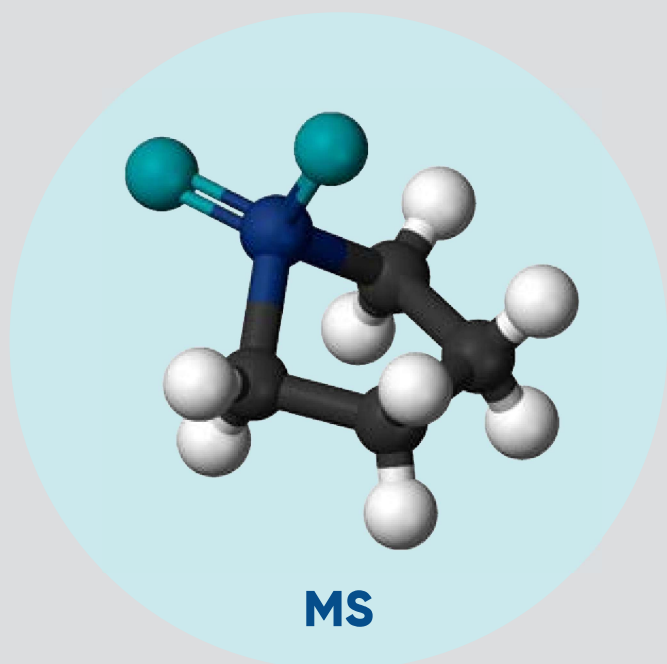
Biocompatibilità <sup>1,2,5,7,200</sup>



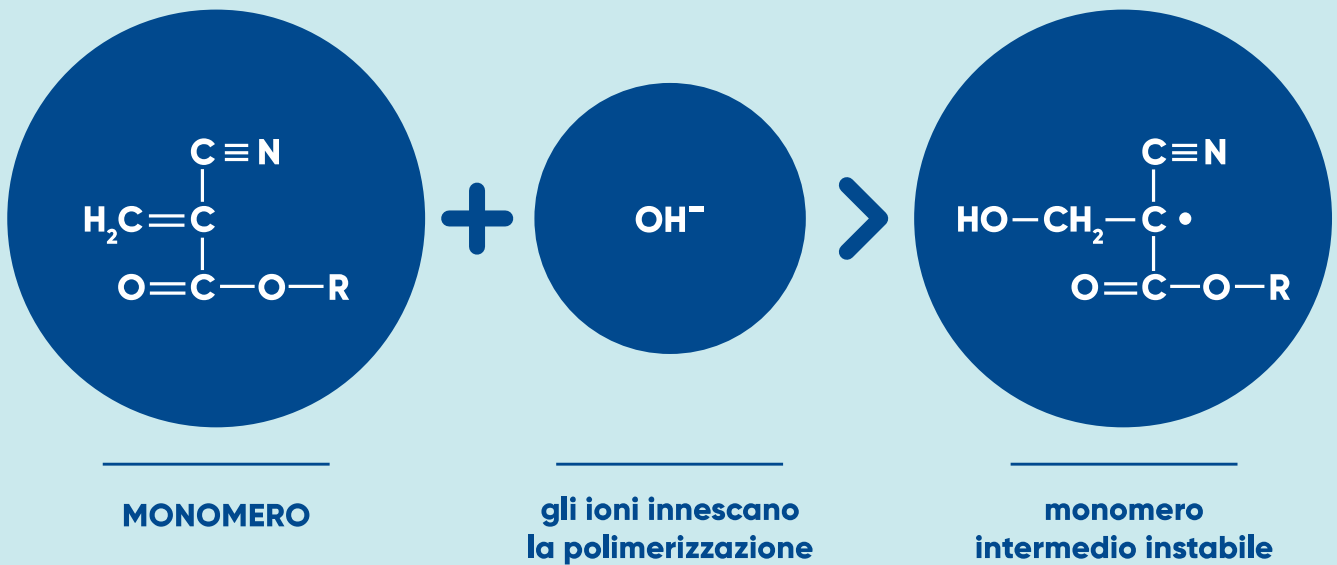
NESSUNA necrosi tissutale <sup>3,7,6,172</sup>



Elasticità della pellicola al termine  
della polimerizzazione <sup>2,7,30,65,84,91</sup>

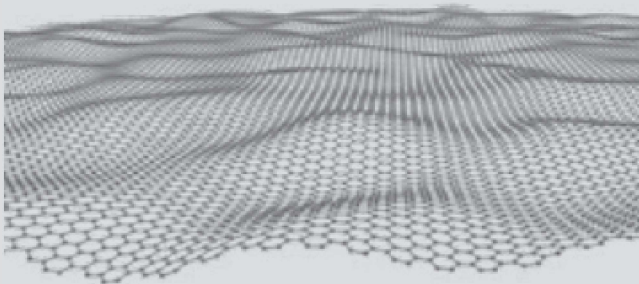




POLIMERIZZAZIONE <sup>192,194,198</sup>

In:

- Ambienti umidi e tessuti
- SANGUE o ALTRI LIQUIDI CORPOREI (siero, linfa, succhi gastrici, pancreatici, bile, saliva, urine)
- Polimerizza dopo 1-2 secondi e termina dopo 60-90 sec



- Durante la polimerizzazione si forma una pellicola elastica e sottile che si adatta all'anatomia dei tessuti. <sup>106-108</sup>
- Al termine della polimerizzazione, la superficie della pellicola non è più adesiva. <sup>8</sup>

NOTA

Acqua distillata/glucosio/mannitolo non attivano la polimerizzazione <sup>3,7,6,172</sup>

The image features a solid teal background. Scattered across the upper half are numerous white circles of varying sizes, some appearing as bright white dots and others as soft, out-of-focus bokeh. A large, white, teardrop-shaped graphic is positioned in the center, resembling a water drop. The text is overlaid on this drop and the background.

**Nessun  
residuo,  
zero tracce.**

# UNA PELLICOLA BIODEGRADABILE.

## DEGRADAZIONE IDROLITICA

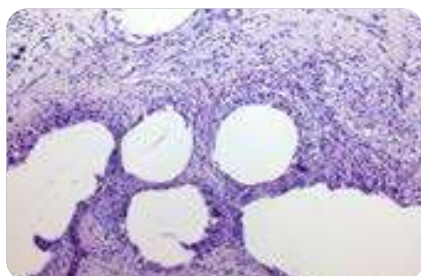
Le carbossilesterasi circolanti nel sangue BIODEGRADANO il Glubran<sup>®</sup> 2 tramite meccanismi idrolitici, in un tempo che va da 15 giorni a 6 mesi.

I prodotti di degradazione sono escreti dal corpo attraverso i reni e l'emuntorio polmonare.<sup>65</sup>

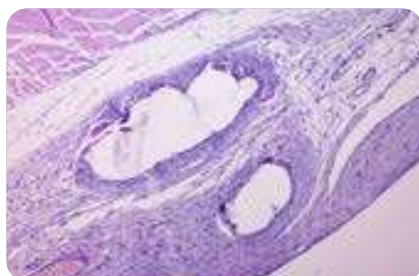
Nei tessuti più vascolarizzati, l'eliminazione è più rapida.<sup>55,200</sup>

### Glubran<sup>®</sup> 2 non arresta il processo di guarigione e di rigenerazione tissutale.

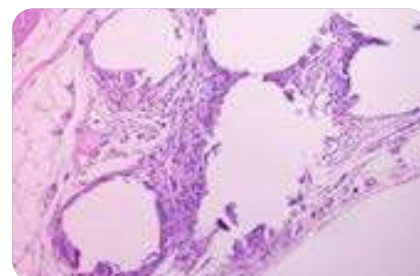
Le stesse cellule tissutali di nuova formazione penetrano nella pellicola di Glubran<sup>®</sup> 2 e continuano a colonizzarla, a riprodursi, fino ad eliminarla.<sup>55,200</sup>



7 GIORNI



15 GIORNI



30 GIORNI

Campioni istologici di sezioni trasversali della parete addominale di ratti sottoposti ad intervento di riparazione di ernia con fissaggio delle protesi effettuato con Glubran<sup>®</sup> 2. Interazione tra fibre della rete protesica e tessuti ospite a 7, 15 e 30 giorni dopo l'intervento chirurgico (Modificato da Poli et Al. 2019).<sup>200</sup>

# UNA GOCCIA DI SICUREZZA.\*

## TEST DI BIOCOMPATIBILITÀ<sup>1</sup>

- Citotossicità
- Genotossicità
- Mutagenicità

## TEST TISSUTALI<sup>1</sup>

- Reattività intracutanea su coniglio
- Sensibilizzazione allergica su cavia
- Test di impianto muscolare nel coniglio

## RISULTATI

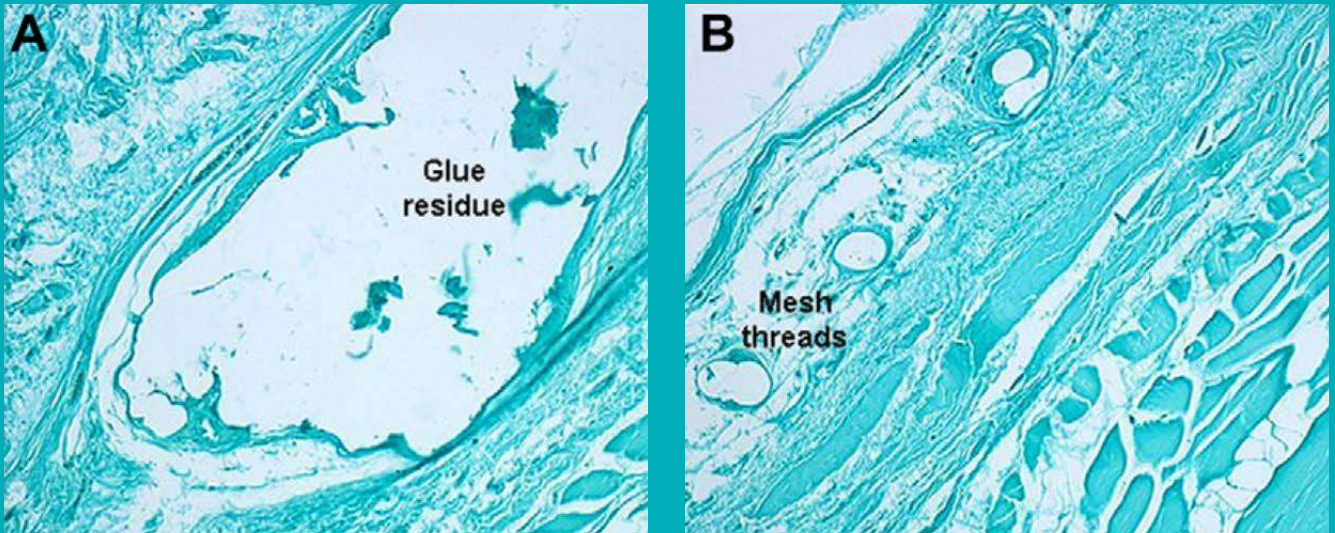
Il prodotto provoca una moderata infiammazione, tipica delle reazioni da corpo estraneo, come i fili da sutura<sup>1,7,200</sup>

NESSUNA infiammazione cronica<sup>1,3,6,7,200</sup>

Completata la polimerizzazione, il Glubran<sup>®</sup> 2 si comporta come BIOMATERIALE INERTE<sup>1,2,7,27,78,202</sup>

- Oltre 2 MLN di trattamenti
- 25 anni di sicurezza
- Oltre 200 pubblicazioni

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



"Colla chirurgica a base di cianoacrilato come alternativa ai punti di sutura nel fissaggio delle reti nella riparazione dell'ernia." <sup>7</sup>

- ... Non sono stati osservati PMN (PoliMorfoNucleati), cellule necrotiche o cellule apoptotiche.
- "...quando furono finalmente sintetizzati cianoacrilati con catene alchiliche più lunghe (degradazione più lunga), questi iniziarono a essere usati clinicamente senza istotossicità..." <sup>192</sup>

# Soluzioni in costante evoluzione.



**1 ml / 0.5 ml / 0.25 ml**

**10 monodose sterili in blister di alluminio**

**Periodo di validità di 2 anni**





# APPLICAZIONI PERSONALIZZATE.

## Ampia gamma di applicatori dedicati.

Dispositivi per applicazioni  
goccia a goccia



Puntale per applicazione  
lineare sottile



Cateteri laparoscopici per applicazione goccia a goccia

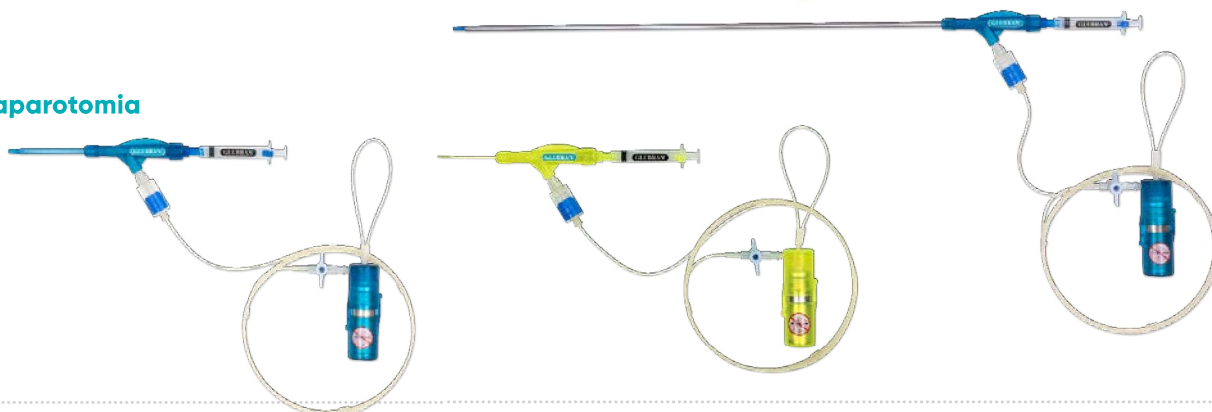


Nebulizzatori per:

Laparoscopia

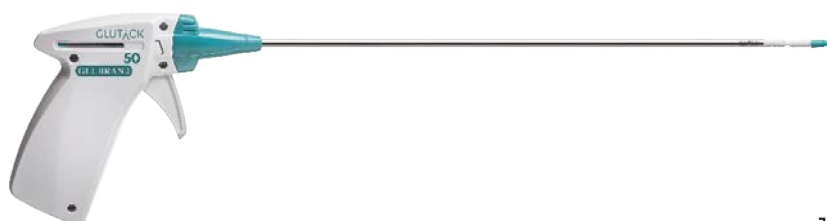


Laparotomia



GLUTACK<sup>®</sup>

Dispositivo di fissaggio  
atraumatico delle protesi  
erniarie per via laparoscopica





# COME SIGILLANTE BATTERIOSTATICO

## CHIRURGIA GENERALE

### Per prevenire e ridurre

Microperdite e stravasi di liquidi con conseguente formazione di fistole, sieromi e linforrea.

### Per sigillare

- Anastomosi (vascolari, gastrointestinali, biliari, urologiche) <sup>2,5,7,29,192,194</sup>
- Suture <sup>7,9,19,26,28,43,47,66,85</sup>
- Linee di resezione manuali e meccaniche <sup>15,63-66,82,106</sup>
- Superfici di resezione di parenchimi e organi (fegato, reni, pancreas, milza, polmoni) <sup>69,70,81,82,85,86,91,95,97,192</sup>
- Cavità chirurgiche in seguito alla rimozione di organi o di masse tumorali <sup>74,84,94,97</sup>

### Per trattare

- Fistole (biliari, anali, perianali, urinarie, faringee, liquorali, bronchiali, pleuriche, esofagee, tracheoesofagee, gastriche, gastrointestinali, duodenali e pancreatiche) <sup>22,32,75-80,88,90,92,99,110-115</sup>

## CHIRURGIA EPATICA

### Per prevenire

La formazione di bilomi e "leaks" biliari dopo interventi di chirurgia epatica e colecistectomia <sup>81,82,152,159</sup>

## CHIRURGIA TORACICA

### Per fare aerostasi

Interventi di resezione polmonare, lobectomie, pneumonectomie, bullectomie, riduzioni di volume, resezioni tracheobronchiali <sup>85-92</sup>

## NEUROCHIRURGIA

### Per sigillare

- Suture di plastiche durali craniche e spinali in associazione ad altri prodotti (garze, spugne emostatiche) <sup>20</sup>
- L'accesso transfenoidale della sella turcica, per rimozione di adenomi ipofisari <sup>21</sup>

## CHIRURGIA DEL SENO E GINECOLOGICA

### Per chiudere e sigillare

- Vasi linfatici sezionati, per prevenire e ridurre la formazione di seromi e linforrea <sup>84,94</sup>





# COME ADESIVO

## CHIRURGIA

### Per fissare

- Protesi erniarie <sup>4,7,9,37-60,93</sup>
- Protesi nella sacrocolpopessi <sup>93</sup>
- Nella plastica vaginale, perineale, uterina <sup>24-25</sup>
- Omento <sup>106-108,204</sup>
- Patch di tessuto (biologico e sintetico) <sup>6,12-14,27,61,105</sup>

### Per sostituire le suture in

- Riparazione di piccole lacerazioni epicardiche <sup>14-16,208</sup>
- Timpanoplastica <sup>24,25</sup>
- Uvuloplastica <sup>28</sup>
- Circoncisione, fimosi e frenulotomia <sup>33-35,103</sup>
- Chiusura dei punti di inserzione dei trocar
- Ferite chirurgiche <sup>10,11,26,47,192,207,20</sup>
- Chirurgia odontoiatrica <sup>22,26,27,193</sup>

### Per incollare

- Tessuti danneggiati <sup>17,27, 205,206</sup>
- Frammenti ossei e osseocartilagine <sup>207</sup>
- Valvole fonatorie tracheoesofagee

### Per occludere

- Fistole
- Dotti (biliari, pancreatici ecc.)
- Canali (linfatici ecc.) <sup>22,32,75-80,88,90,92,99,110,115</sup>



## COME EMOSTATICO

### PER TUTTI I TIPI DI INTERVENTI CHIRURGICI

- Blocca sanguinamenti a nappo
- Aderisce saldamente ai siti emorragici
- Si adatta alle micro-pieghe dei tessuti

### Una soluzione semplice ed efficace per raggiungere una rapida emostasi in 7,62,63,95-97-116-119,121-127,131-134

- Lesioni con sanguinamento a nappo dopo chirurgia oncologica con rimozione parziale o totale di un organo
- Superfici di resezione di vari organi (fegato, reni, milza, pancreas, polmone)
- Anastomosi vascolari e cardiocirurgiche (bypass arterioso e venoso, fistole arterovenose, protesico-vascolare, riparazione di aneurismi)
- Superfici orofaringee sanguinanti
- Tessuti parenchimatosi su lacerazioni, lesioni emorragiche
- Letto della colecisti, della vescica
- Cisti ovariche, miomectomie, isterectomia
- Ulcere gastro-duodenali, con iniezione endoscopica nella sottomucosa



## COME SCLEROSANTE

### Partner dell'endoscopista <sup>110-190</sup>

Iniettandolo all'interno delle varici (Esofagee, Gastriche, Duodenali) polimerizza ed occlude il vaso, inducendo la sclerosi. <sup>5,113,128-132,135</sup>

#### VARICE SANGUINANTE

1. Sanguinamento della Varice
2. Iniezione di Glubran<sup>®</sup> 2
3. **Varice Occlusa**

Trattamento endoscopico di varici gastriche  
(Autore Prof. G. Battaglia)



1.



2.



3.



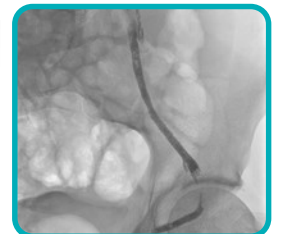
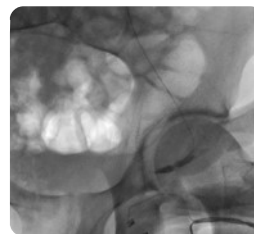
## COME AGENTE EMBOLIZZANTE LIQUIDO

### Partner dei radiologi interventisti (corpo e testa-collo) <sup>3,6,77,87,110,118,121,125,134,137-190</sup>

- Iniettato nel vaso sanguigno, polimerizza, formando uno stampo aderente alle pareti del vaso ostruendolo e causando un'occlusione definitiva senza ricanalizzazioni.

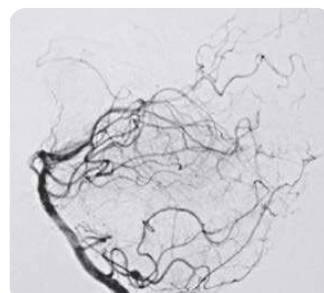
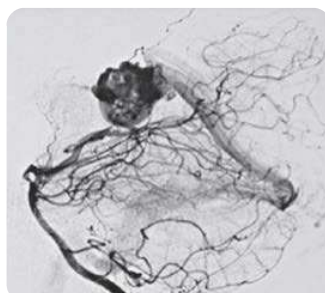
#### VARICOCELE <sup>142</sup>

Pre-embolizzazione  
Microcateterizzazione  
**Post-embolizzazione**



#### EMBOLOGIAZIONE DI UNA MAV <sup>142,190</sup>

Sanguinamento della MAV prima e dopo l'iniezione del Glubran<sup>®</sup> 2 con l'ottenimento di una **completa obliterazione e risoluzione**.



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# UNA QUALITÀ CERTIFICATA.

**Grazie agli sforzi condivisi di un team di professionisti nella certificazione clinica e normativa**, il sistema di qualità e processo produttivo di GEM ha ottenuto la certificazione

ISO 13485:2016 e ISO 9001:2015. GEM ha inoltre la certificazione MDSAP in quanto i dispositivi prodotti sono autorizzati per la vendita in Canada, Brasile e Australia.



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