Experts for medical co-operations.

hcp

GLUBRAN®2

Die sanfte Kraft eines Tropfens.

—

Medizinprodukt der Klasse III, synthetisch, CE-zertifiziert für den chirurgischen und endovaskulären Gebrauch

GEM SOLUTION COMES FROM EVOLUTION.

Inhaltsverzeichnis

UNTERSTÜTZUNG DES CHIRURGEN FÜR BESSERE PATIENTENERGEBNISSE.

Seit 25 Jahren unterstützen wir die Chirurgie.

GEM ist das Ergebnis unseres andauernden Engagements in der Forschung und unseren Bemühungen, unsere Produkte zu verbessern und ihre Wirksamkeit und Qualität anhand der Beiträge unserer Fachleute und durch klinische Studien über die innovativsten Geräte nachzuweisen.

ADHÄSIV

VERSIEGELND

HÄMOSTATISCH

BAKTERIOSTATISCH

SKLEROSIEREND

EMBOLISIEREND

EINE REVOLUTION, IN EINEM TROPFEN.

Glubran 2 für die minimal-invasive Chirurgie.

- **Vielseitig, polymerisiert bei Kontakt mit dem Gewebe und in feuchter Umgebung schnell** [59,98,100,159]
- **Bildet einen dünnen, elastischen, atmungsaktiven Film, der fest am Gewebe oder prothetischen Materialien haftet** [2,7,30,65,84,91]

EINZIGARTIGE FORMEL im Handel erhältlich

Ein durch den Zusatz eines Monomers modifiziertes Produkt der zweiten Generation

N-Butyl 2 Cyanoacrylat (NBCA)+ Methacryloxysulfolan (MS)

SECHS PRODUKTE IN EINEM TROPFEN.

SECHS Eigenschaften in EINEM EINZIGEN Produkt, für mehr als 80 chirurgische Anwendungen.

ADHÄSIV

Hohe Zugfestigkeit: die zulässige Mindestbelastung beträgt 435 N [circa 18 Kg/cm^2] [1,2,13,16]

VERSIEGELND

Mithilfe spezieller Sprühapplikatoren aufgetragen, bildet es dank seinem synthetischen Charakter und seiner hohen Haftkraft einen dünnen versiegelnden und wasserabweisenden Film [2,27,30,64-68,77,88,91,106-108]

HÄMOSTATISCH

Reagiert auch mit ungeronnenem Blut und löst eine „mechanische" Blutstillung an der blutenden Stelle aus. [7,62,63,95-97-116-119,121-127,131-134]

BAKTERIOSTATISCH

Hemmt die Proliferation von Bakterien für durchschnittlich 7 Tage. [1,5,7,10,11,28, 34,76,115]

SKLEROSIEREND

Nach Injektion in das Lumen des Gefäßes/der Varize polymerisiert es und bewirkt eine lokale Thrombose und in der Folge eine Fibrose und Sklerose. [5,113,128-132,135]

EMBOLISIERENDE FLÜSSIGKEIT

Nach Injektion in das Blutgefäß polymerisiert es und nimmt eine an den Gefäßwänden haftende und das Gefäß verstopfende Form an. Dadurch entsteht eine endgültige Okklusion, die einer chirurgischen Ligatur entspricht. [3,6,77,87,110,118,121,125,134,137-190]


Radiologie, Neuroradiologie und interventionelle Kardiologie
Magen-Darm-Endoskopie
Kardiochirurgie
Neurochirurgie
Embolisierend
Sklerosierend
Gynäkologische Chirurgie
Bakteriostatisch
GLUBRAN®2
Hämostatisch
Vaskuläre Chirurgie
Urologische Chirurgie
Versiegelnd
Adhäsiv
HNO
CHIRURGIE
Allgemeinchirurgie
Thoraxchirurgie
Pädiatrische Chirurgie
Plastische Chirurgie

Wenn es einen Unterschied macht.

EIN ECHTER KLEBSTOFF UND EINE OPTIMALE BAKTERIOSTATISCHE VERSIEGELUNG.*

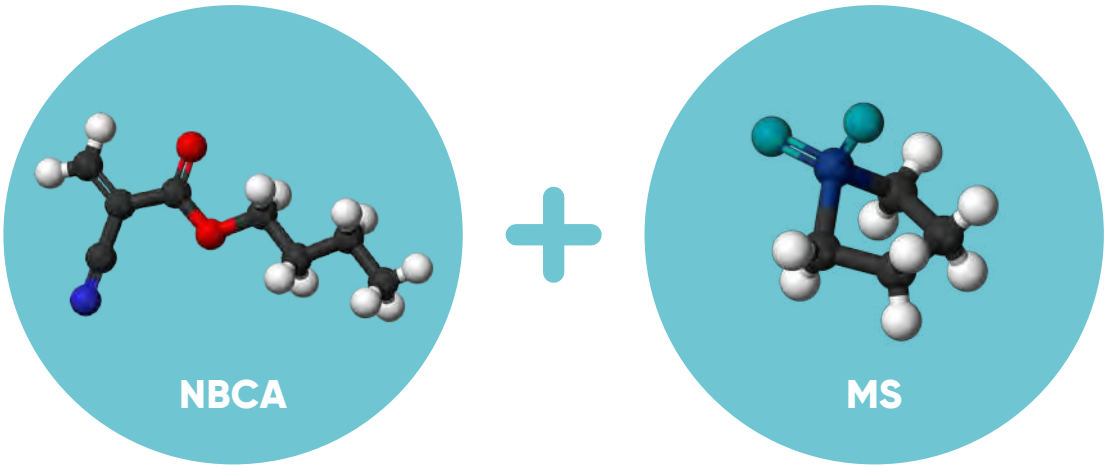
- **Es interagiert und reagiert auch mit anderen Flüssigkeiten als Blut: Serum, Lymphe, Magensäure, Pankreassaft, Galle, Speichel, Urin.**

- **Reagiert auch mit ungeronnenem Blut und löst eine „mechanische“ Blutstillung an der blutenden Stelle aus.** [63-84,95,98-109,197]

- **Die Hämostase ist immer gewährleistet, auch bei antikoagulierten Patienten oder Patienten mit erblichen Koagulopathien.** [103,143,146,161]

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

EINE ZUVERLÄSSIGE BIOCHEMIE.



Erscheinungsbild
DURCHSICHTIG

Geruch
TYPISCH FÜR CYANOACRYLAT

Viskosität
ÄHNLICH WIE WASSER [1]

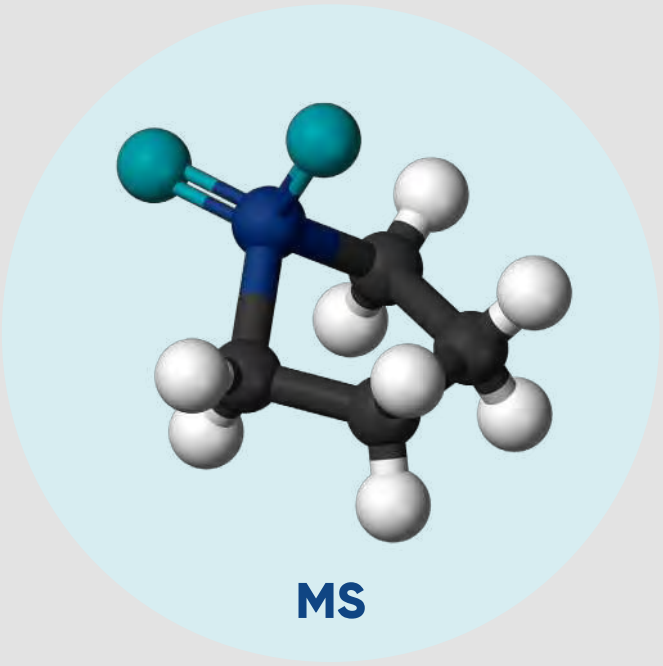
- **Gebrauchsfertig** [1,7,35,37,196]
- **Polymerisiert NICHT in Gegenwart von Luft** [142]
- **Lagertemperatur, +2 bis +8°C**
- **Kann für 5 Tage bei Raumtemperatur (22,5+/-2,5 °C) aufbewahrt werden** [1]
- **Wirksam in feuchter Umgebung** [1,59,98,100,159]

Vorteile von MS:

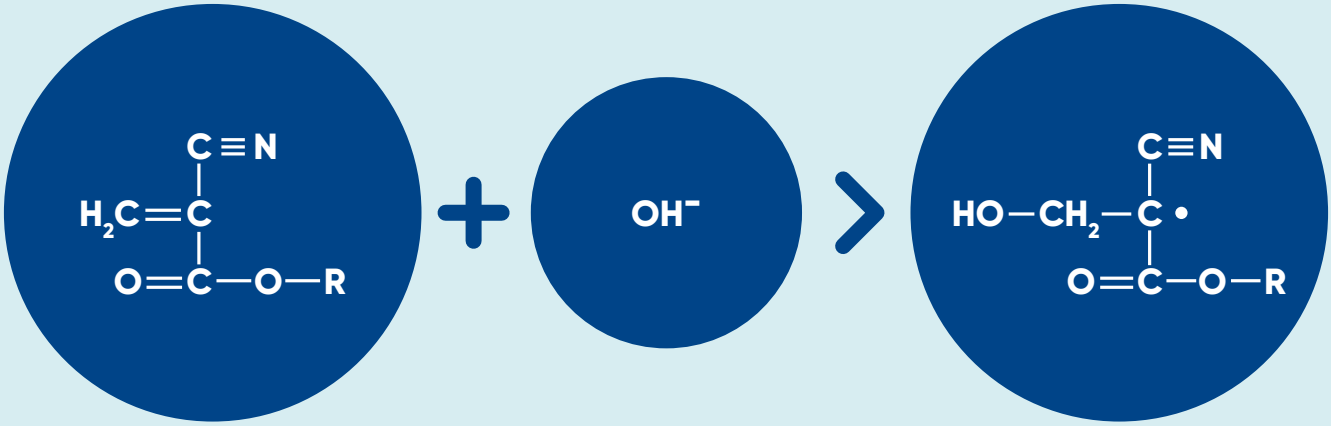
- Polymerisationstemperatur:

  45°C, viel niedriger als die 80-90°C, die bei reinen monomeren Cyanoacrylaten üblich sind. [6,8,59, 98,100,159]

- Biokompatibilität [1,2,5,7,200]
- KEINE Gewebsnekrose [3,7,6,172]
- Nach der Polymerisation ist der Film elastisch [2,7,30,65,84,91]



POLYMERISATION [192,194,198]



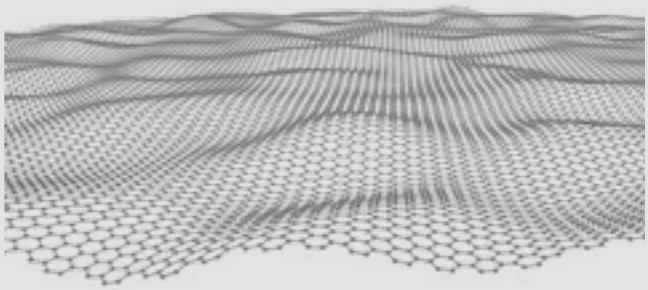
MONOMER

die Polymerisation wird durch Ionen ausgelöst

instabiles Zwischenmonomer

In:

- **Feuchter Umgebung oder Geweben**
- **BLUT oder ANDEREN KÖRPERFLÜSSIGKEITEN (Serum, Lymphe, Magensäure, Pankreassaft, Galle, Speichel, Urin)**
- **Polymerisiert nach 1-2 Sekunden und endet nach 60-90 Sekunden**



- Während der Polymerisation bildet sich ein dünner, elastischer Film, der sich der Gewebeanatomie anpasst. [106-108]
- Nach der Polymerisation ist die Oberfläche des Films nicht mehr klebrig. [8]

HINWEIS

Die Polymerisation wird nicht durch destilliertes Wasser/Glukose/Mannitol aktiviert [3,7,6,172]


Keine
Rückstände,
keine
Spuren.

EIN BIOLOGISCH ABBAUBARER FILM.

HYDROLYTISCHER ABBAU

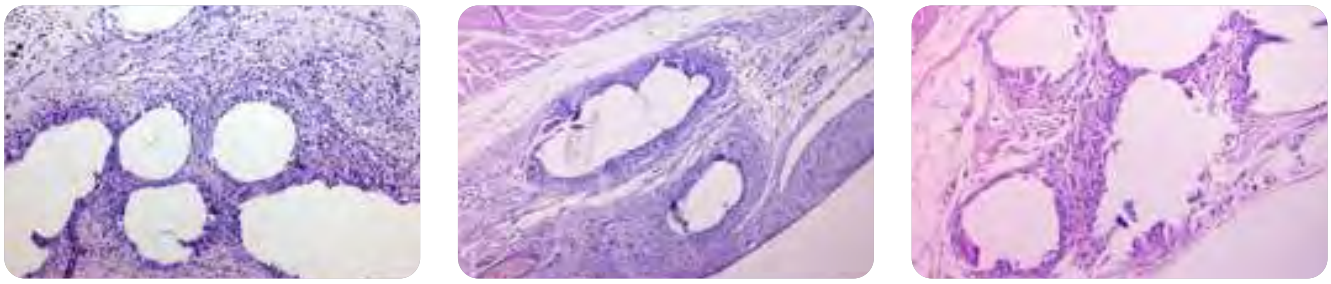
Im Blut zirkulierende Carboxylesterasen BAUEN Glubran® 2 durch hydrolytische Mechanismen innerhalb von 15 Tagen bis 6 Monaten BIOLOGISCH ab.

Die Abbauprodukte werden über die Nieren und die Lungen aus dem Körper ausgeschieden. [65]

In stärker vaskularisierten Geweben erfolgt die Ausscheidung schneller. [55,200]

Glubran® 2 unterbricht die Heilung und die Geweberegeneration nicht.

Die neu gebildeten Gewebezellen dringen in den Glubran® 2 Film ein, kolonisieren ihn und vermehren sich, bis der Film eliminiert wird. [55,200]



7 TAGE | **15 TAGE** | **30 TAGE**

Histologische Proben von Bauchwandquerschnitten von Ratten, die einer Hernienreparatur mit prothetischer Fixierung mit Glubran® 2 unterzogen wurden. Wechselwirkung zwischen prothetischen Netzfasern und dem Wirtsgewebe 7, 15 und 30 Tage nach dem chirurgischen Eingriff (Geändert durch Poli et Al. 2019). [200]

EIN TROPFEN SICHERHEIT.*

BIOKOMPATIBILITÄTSTEST [1]

- Zytotoxizität
- Genotoxizität
- Mutagenität

GEWEBETESTS [1]

- Intrakutane Reaktivität beim Kaninchen
- Allergische Sensibilisierung am Meerschweinchen
- Muskelimplantationstest beim Kaninchen

ERGEBNISSE

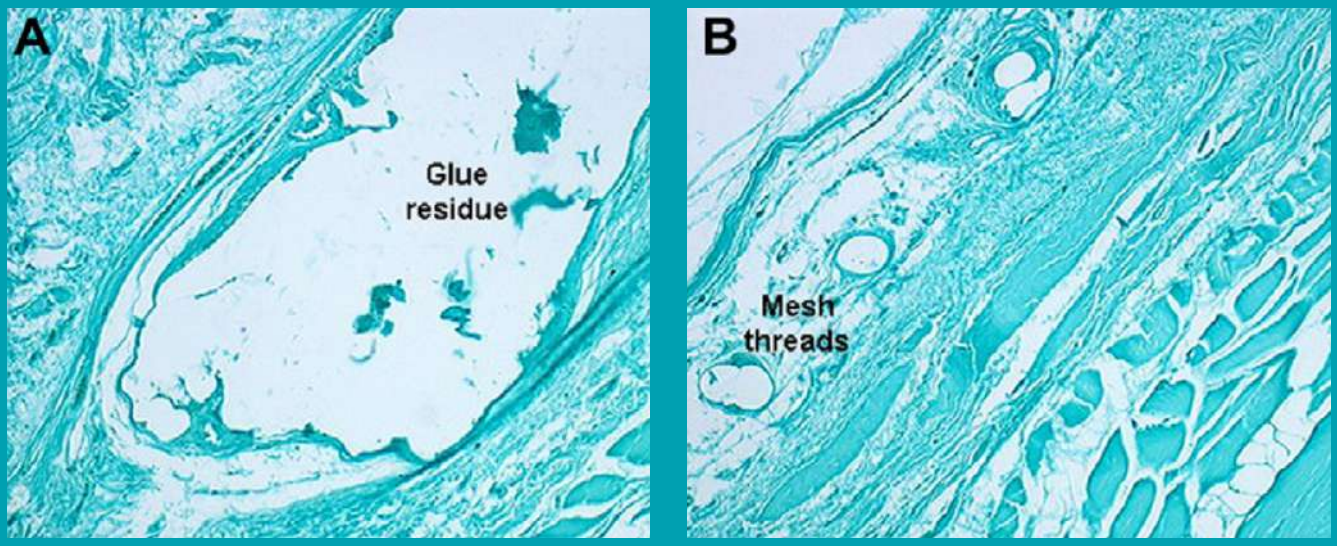
Das Produkt verursacht eine mäßige Entzündung, die bei Fremdkörperreaktionen, wie z. B. Nahtmaterial, üblich ist [1,7,200]

KEINE chronische Entzündung. [1,3,6,7,200]

Nach der Polymerisation verhält sich Glubran® 2 wie ein INERTES BIOMATERIAL [1,2,7,27,78,202]

- Mehr als 2 MIO Behandlungen
- 25 Jahre Sicherheit
- Über 200 Veröffentlichungen

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



„Chirurgischer Kleber aus Cyanoacrylat als Alternative zu Nahtmaterial bei der Fixierung von Netzimplantaten bei Hernienreparationen. " [7]

- **... Es wurden keine polymorphkernige (PMN), nekrotische oder apoptotische Zellen nachgewiesen.**
- *„...nachdem endlich Cyanoayrylate mit längeren Alkylketten synthetisiert wurden (längerer Abbau), fing man an, diese klinisch ohne Histotoxizität einzusetzen...“* [192]

Ständig weiterentwickelte Lösungen.

G-NB-2

G-NB-50

G-NB2S-25

1 ml / 0.5 ml / 0.25 ml

10 sterile Einzeldosen in Aluminiumblisterpackung

Haltbarkeit von 2 Jahren

BENUTZERDEFINIERTE ANWENDUNGEN.

Große Auswahl an spezifischen Applikatoren.

Vorrichtungen zur Drop-by-Drop-Anwendung

› G2-DCD-210-8T

› G-LLS

Spitze für dünne lineare Anwendung

› G-DT

Laparoskopische Katheter zur Drop-by-Drop-Anwendung

› G2-LPC

› G2-LPC-RIG

Sprühapplikatoren für:

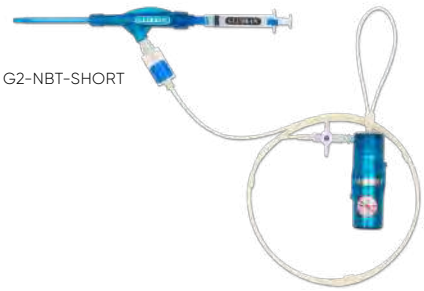
Laparoskopie

› G2-NBT

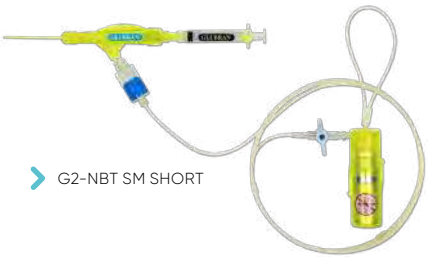
› G2-NBT-SMALL

› G2-NBT RIG

Laparotomie



› G2-NBT-SHORT



› G2-NBT SM SHORT

GLUTÄCK

Laparoskopische atraumatische Fiziervorrichtung für Hernienimplantate

› GB-DS-30
GB-DS-60

› GB-DS SH 30
GB-DS SH 60

18/19

ALS BAKTERIOSTATISCHES VERSIEGELUNGSMITTEL

ALLGEMEINCHIRURGIE

Zur Vermeidung und Reduzierung von

Mikroleckagen und Überlauf von Flüssigkeiten mit daraus resultierender Bildung von Fisteln,Seromen und Lymphorrhoe.

Zur Versiegelung von

- Anastomosen (vaskuläre, gastrointestinale, biliäre, urologische). [2,5,7,29,192,194]
- Nähten. [7,9,19,26,28,43,47,66,85]
- Manuellen und mechanischen Resektionslinien. [15,63-66,82,106]
- Resektionsflächen von Parenchymen und Organen (Leber, Nieren, Bauchspeicheldrüse, Milz, Lunge). [69,70,81,82,85,86,91,95,97,192]
- Chirurgischen Hohlräumen nach Entfernung von Organen oder Geschwülsten. [74,84,94,97]

Zur Behandlung von

- Fisteln (biliäre, anale, perianale, urinale, pharyngeale, Liquor, bronchiale, pleurale, ösophageale, tracheoösophageale, gastrische, gastrointestinale, duodenale und pankreatische). [22,32,75-80,88,90,92,99,110-115]

LEBERCHIRURGIE

Zur Vermeidung

Der Bildung von Biliomen und biliären „Leckagen“ nach Leberoperationen und Cholezystektomie.[81,82,152,159]

THORAXCHIRURGIE

Zur Aerostase

Lungenresektionen, Lobektomien, Pneumonektomien, Bullektomien, Volumenreduktionen Tracheobronchialresektionen. [85-92]

NEUROCHIRURGIE

Zur Versiegelung

- Der Nähte von kranialen und spinalen Duralplastiken in Kombination mit anderen Produkten (Gaze, hämostatische Schwämme). [20]
- Des transsphenoidalen Zugangs des Türkensattels, zur Entfernung von Hypophysenadenomen. [21]

BRUST- UND GYNÄKOLOGISCHE CHIRURGIE

Zum Verschließen und Versiegeln

- Sektionierter Lymphgefäße, zur Vermeidung und Verminderung der Bildung von Seromen und Lymphorrhoe. [84,94]

ALS KLEBER

CHIRURGIE

Zur Fixierung von

- Hernienimplantaten. [4,7,9,37-60,93]
- Implantate in der Sakrokolpopexie. [93]
- In der Vaginal-, Damm- und Gebärmutterplastik. [24-25]
- Omentum. [106-108,204]
- Gewebepatch (biologisches und synthetisches). [6,12-14,27,61,105]

Als Ersatz von Nahtmaterial der

- Behandlung kleiner epikardialer Risswunden. [14-16,208]
- Tympanoplastik. [24,25]
- Uvulaplastik. [28]
- Beschneidung, Phimose und Frenulotomie. [33-35,103]
- Verschluss von Trokar-Einführungsstellen.
- Chirurgische Wunden. [10,11,26,47,192,207,20]
- Zahnmedizinische Chirurgie. [22,26,27,193]

Zum Verkleben von

- Beschädigten Geweben. [17,27, 205,206]
- Knochenfragmenten und Knochenknorpel. [207]
- Tracheo-ösophagealen phonatorischen Klappen.

Zum Verschließen von

- Fisteln
- Gallen-, Pankreasgang usw.
- Lymphbahnen usw. [22,32,75-80,88,90,92,99,110,115]

ALS HÄMOSTATIKUM

FÜR ALLE CHIRURGISCHEN EINGRIFFE

- Stillt Sickerblutungen.
- Haftet fest an blutenden Stellen.
- Passt sich an kleinste Falten im Gewebe an.

Eine einfache und effektive Lösung zur schnellen Hämostase bei [7,62,63,95-97-116-119,121-127,131-134]

- Verletzungen mit Sickerblutungen nach onkologischen Operationen mit teilweiser oder vollständiger Entfernung eines Organs.
- Resektionsflächen von Organen (Leber, Nieren, Milz, Bauchspeicheldrüse, Lunge).
- Vaskulären und kardialen Anastomosen (arterieller und venöser Bypass, arteriovenöse Fisteln, prothetisch-vaskuläre, Aneurysmareparatur).
- Blutenden oropharyngealen Flächen.
- Parenchymgewebe an Risswunden, hämorrhagischen Läsionen.
- Gallenblasenbett, Blasenbett.
- Ovarialzysten, Myomektomien, Hysterektomien.
- Gastroduodenalen Ulzera, mit endoskopischer Injektion in die Submukosa.

ALS SKLEROSIERUNGSMITTEL

Partner von Endoskopikern [110-190]

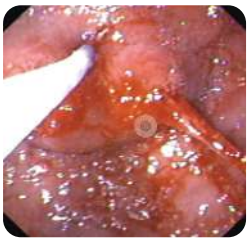
Nach Injektion in Varizen (Speiseröhre, Magen, Zwölffingerdarm) polymerisiert es und verschließt das Gefäß, was zur Sklerose führt. [5,113,128-132,135]

BLUTENDE VARIZE

1. Blutung der Varize
2. Injektion von Glubran® 2
3. **Okkludierte Varize**

Endoskopische Behandlung von Magenvarizen (Autor Prof. G. Battaglia)

1.



2.

3.

ALS FLÜSSIGES EMBOLISIERUNGSMITTEL

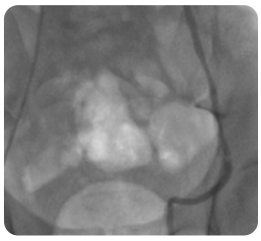
Partner von interventionellen Radiologen (Körper und Kopf-Halsbereich)

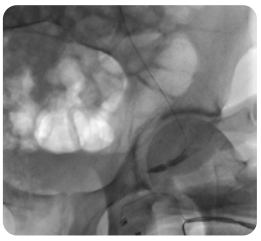
[3,6,77,87,110,118,121,125,134, 137-190]

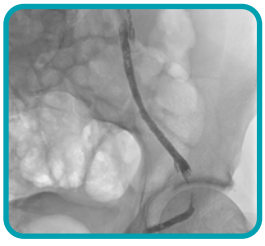
- Nach Injektion in das Blutgefäß polymerisiert es und nimmt eine an den Gefäßwänden haftende und das Gefäß endgültig verstopfende Form ohne Rekanalisation an.

VARIKOZELE [142]

Prä-Embolisation
Mikro-Katheterisierung
Post-Embolisation

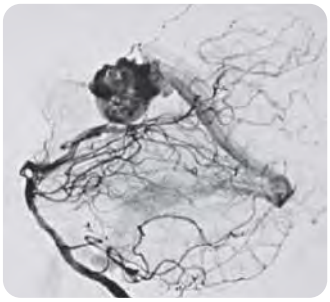


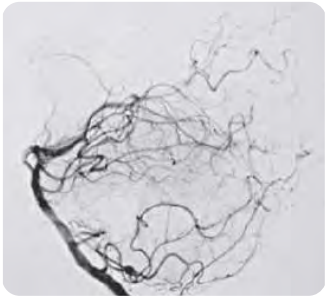


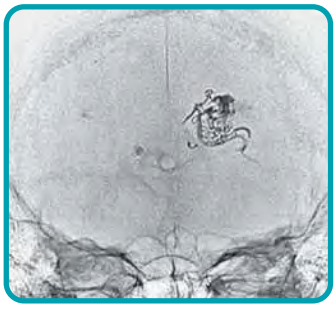


EMBOLISATION EINER AVM [142,190]

Blutung der AVM vor und nach der Injektion von Glubran® 2 mit **vollständiger Verschluss uns Auflösung.**







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Kardiochirurgie

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ZERTIFIZIERTE QUALITÄT.

Dank der Zusammenarbeit eines Teams von Zertifizierungsfachleuten im klinischen und behördlichen Bereich, haben das Qualitätssystem und der Produktionsprozess von GEM die folgenden Zertifizierungen erworben:

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