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Technology at the service of surgical quality

New devices improve the surgery and the patient outcomes

CONGRESS REPORT

GEM

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Introduction

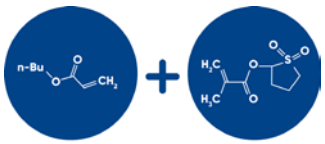
Moderators
Vincenzo Ambrogi, Paolo Delrio, Raimondo Di Giacomo, Gennaro Nasti

During the 2019 Congress of the Italian Society of Oncological Surgery (SICO), GEM S.r.l., an Italian company present internationally in the field of surgical medical devices for over 20 years, organized an interesting symposium focusing on surgical uses of Glubran®2, an innovative sealant with a wide range of indications in surgery, but also endoscopy and interventional radiology/neuroradiology (as a rapidly acting embolization agent).
Glubran®2 is a synthetic surgical adhesive (N-butyl 2-cyanoacrylate/methacryloxysulfolane co-monomer – CE certified class III medical device) with peculiar properties that make it more than just a "strong adhesive" (see the box and the GEM website: www.gemitaly.it for more information and an extensive bibliography).
Moreover, new devices are available that make the application of Glubran®2 easier, safer and more effective; in particular, in addition to the various types of nebulizer (Fig. 1), there are now the following:

a) Glutack® (Fig. 2), a device that allows Glubran®2 to be applied as calibrated drops for the atraumatic fixing of hernia prostheses in laparoscopic surgery;
b) Rutilight® (Fig. 3), a luminous ring featuring LED technology, adaptable to any surgical instrument with a diameter of between 5 and 8 mm; this light provides optimal illumination even of fields that are difficult to access, and thus enhances the surgeon's dexterity.

The GEM Symposium was well attended with the audience showing a lively interest in the topics covered and the distinguished speakers' accounts of their clinical experience with Glubran®2, used in digestive surgery ("sealing" and "reinforcement" of intestinal anastomoses), abdominal hernia surgery (adhesive anchorage of the mesh), thoracic surgery (prevention of air leaks), and breast surgery (prevention of axillary seroma formation).

GLUBRAN®2 [CO-MONOMER]



NBCA MS

- **High power of adhesion in humid environments (vital tissues) with hemostatic, sealant and bacteriostatic (barrier) properties**
- **High elasticity and tensile strength for impermeable and breathable bonding**
- **Ready to use, formulated as a transparent liquid in single-dose containers 0.25; 0.50; 1 ml to be stored at between 2 and 8 °C**
- **Disposable applicator devices for use in open and laparoscopic surgery:**
  - applicator tip for topical distribution of the product
  - blunt-ended needle for drop-by-drop application
  - 1 ml syringe with Luer attachment
  - laparoscopic catheter rigid and flexible for 5 mm trocars
  - nebulizers with autonomous gas propulsion (Figure 1)
- **Low polymerization temperature (45 °C); polymerization begins on contact with the tissues (1-2 seconds) and is completed within 60-90 seconds**
- **Minimal amount required: 1 ml for 20 cm² of tissue**
- **High biocompatibility and slow biodegradability**
- **Can also be applied in combination with sutures/staples**
- **Easily pierced by suture needles**
- **Can be mixed with Lipiodol® for use in endovascular procedures as an embolization agent**
- **Resistant to the aggression of organic proteolytic liquids as gastric, bile, pancreatic juices and of urine and feces.**

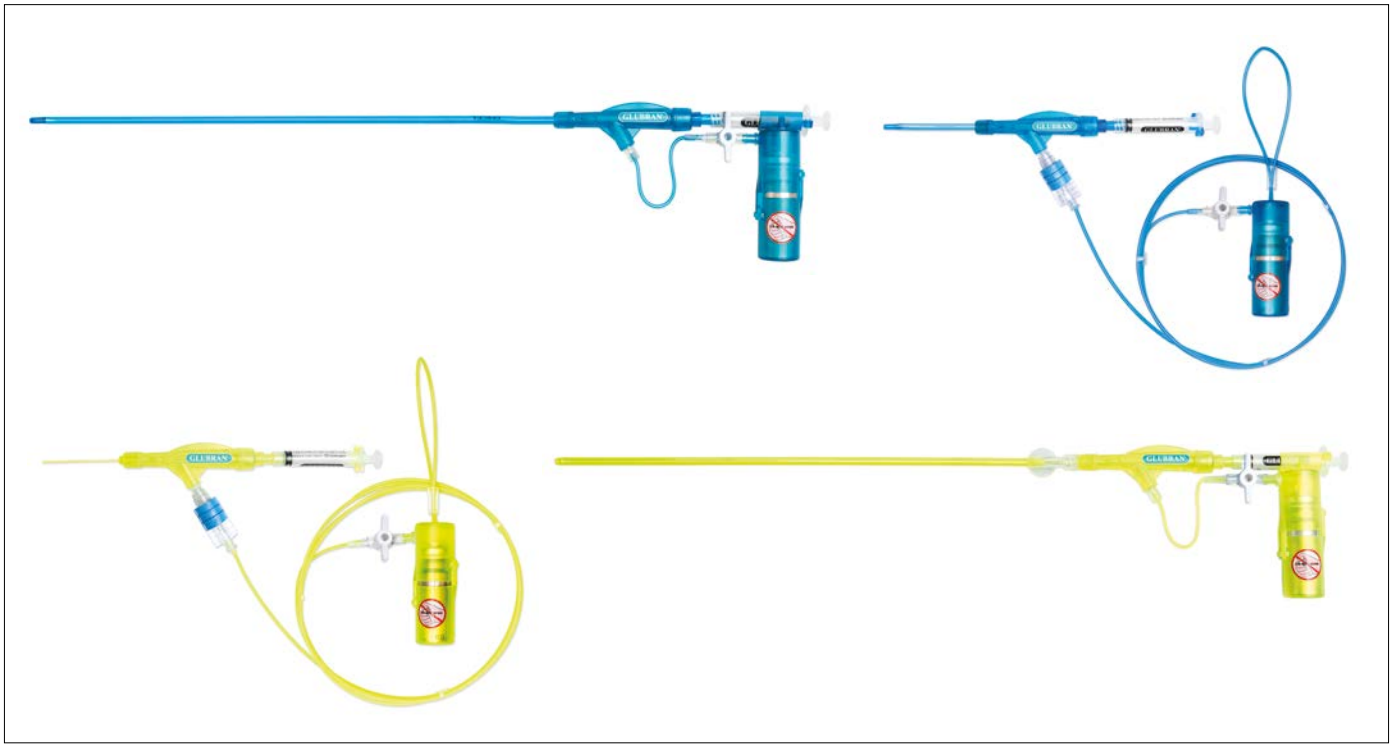


Figure 1 – *Some models of disposable nebulizers with autonomous gas propulsion (spray) for the application of Glubran®2 in open and minimally invasive surgery (laparo/thoracoscopic and robotic), both on large surfaces (blue) and, in the small/short small (yellow) version, on small surfaces and/or in hidden and difficult to reach areas (the characteristics and specific indications of the various applicators are described in detail on the manufacturer 's website).*

Figure 2 – *Glutack®. Device for atraumatic fixing of hernia prostheses. With each press/release of the trigger, it delivers a calibrated drop of Glubran®2, obtaining effective adhesive anchorage of hernioplasty meshes.*

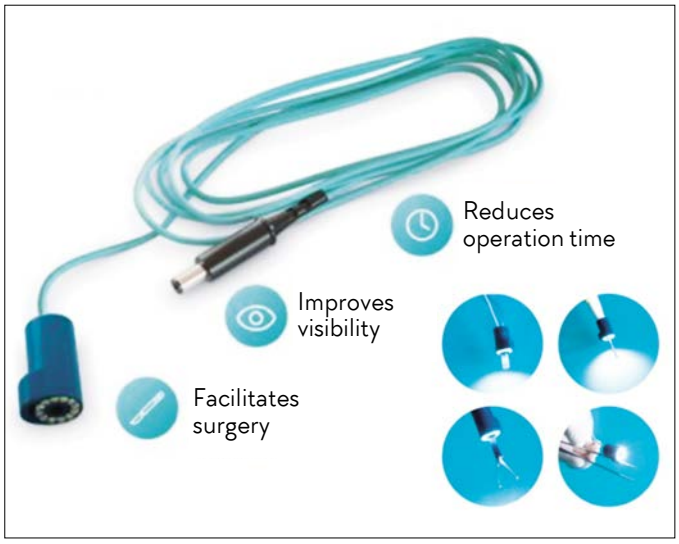


Figure 3 – *Rutilight®. Light ring with LED technology adaptable to any surgical instrument with a diameter from 5 to 8 mm. The device illuminates the surgical field optimally, comfortable and practical, allowing you to work easily even in poorly lit areas.*

ANASTOSEAL: the nebulizer that makes the sealing of the intestinal anastomosis effective. Preliminary results

Daniela Rega

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Around 30% of post-operative morbidity in colorectal surgery can be attributed to anastomotic dehiscence, whose incidence ranges from 1.8% to 15.9% [1, 2, 3]. Fistula prevention therefore has a favorable impact on clinical outcomes. It also helps to contain healthcare costs; indeed, it is estimated that the therapeutic management of a patient with anastomotic dehiscence (further surgery, ICU admission, lengthier hospitalization) costs, on average, five times more than that of a patient with an uncomplicated post-operative course [4, 5].

Effective prevention of anastomotic leaks is based mainly on knowledge of the repair mechanisms that lead to healing of intestinal anastomoses. It is therefore crucially important to identify and correct any patient-related risk factors, primarily protein-calorie malnutrition. Knowledge also guides surgical practice, in which it remains fundamental to use the most technologically advanced mechanical staplers and to apply a technique designed to minimize intraoperative risk factors (this means delicate/atraumatic or no-touch tissue manipulation, richly vascularized and tension-free anastomotic margins, careful control of hemostasis)[6, 7]. Finally, effective prevention can also potentially be achieved through the use of targeted intraoperative procedures, such as the placement of manual stitches in addition to the mechanical suture and/or collagen patches (properly called reinforcement, this is also known as buttressing), or the use of sealants (fibrin glues or sealants like Glubran®2). In this regard, the findings of a recent study[8] on the management of intraoperative colorectal anastomotic leaks (over 450 patients treated by 156 surgeons across 8 countries) indicated that oversewing of the mechanical staple line (77.5%) was preferred over application of a sealant (17.5%), creation of a new anastomosis (9.4%), or just performing an ileostomy or colostomy (10.3%).

Nevertheless, dehiscence occurred in 13% of the cases, most frequently between day IV and day VII post-surgery; notably, the highest percentage of post-operative fistulas occurred in patients managed with a new anastomosis. Sealant may therefore potentially play a role in "preventing" anastomotic leaks in colorectal surgery (Fig. 4). In fact, in experimental studies, Glubran®2 has been found to be particularly suitable for "reinforcing" intestinal anastomoses (manual or intracorporeal linear): applied on the suture line, this modified cyanoacrylate (co-monomer) closes the spaces between one staple and the next,
thus exerting an adhesive, hemostatic and sealing action on the tissues and at the same time forming an effective bacteriostatic barrier. Its clinical efficacy is supported by "promising" although not conclusive evidence, mainly obtained in bariatric surgery. This strengthens the rationale for designing and conducting *ad hoc* studies like ANASTOSEAL (Seal and strengthen intestinal anastomosis in oncological colorectal surgery - ClinicalTrials.gov Identifier: NCT03380858).

ANASTOSEAL is a cohort observational, prospective, multicenter trial coordinated by the "Fondazione G. Pascale" National Cancer Institute in Naples. The primary endpoint of the study is the incidence, in elective colorectal cancer surgery, of post-operative (within the 10th day) dehiscence of anastomoses "reinforced" with Glubran®2 (comparing the results with historical literature data). To allow objective and standardized measurement of the true anastomotic sealing effect, which is to say the added value of Glubran®2, it was decided to evaluate ileocolic anastomoses (mechanical or manual). A main objective of the study was to correlate fistula appearance with any pre-existing risk factors (malnutrition, immunosuppression, cortisone or NSAID therapy, diabetes, previous pelvic radiation therapy). Secondary endpoints are the incidence of perianastomotic bleeding and the appearance of signs of infection indicative of or constituting "precursors" of anastomotic dehiscence (fever, pain, tachycardia, peritonism,

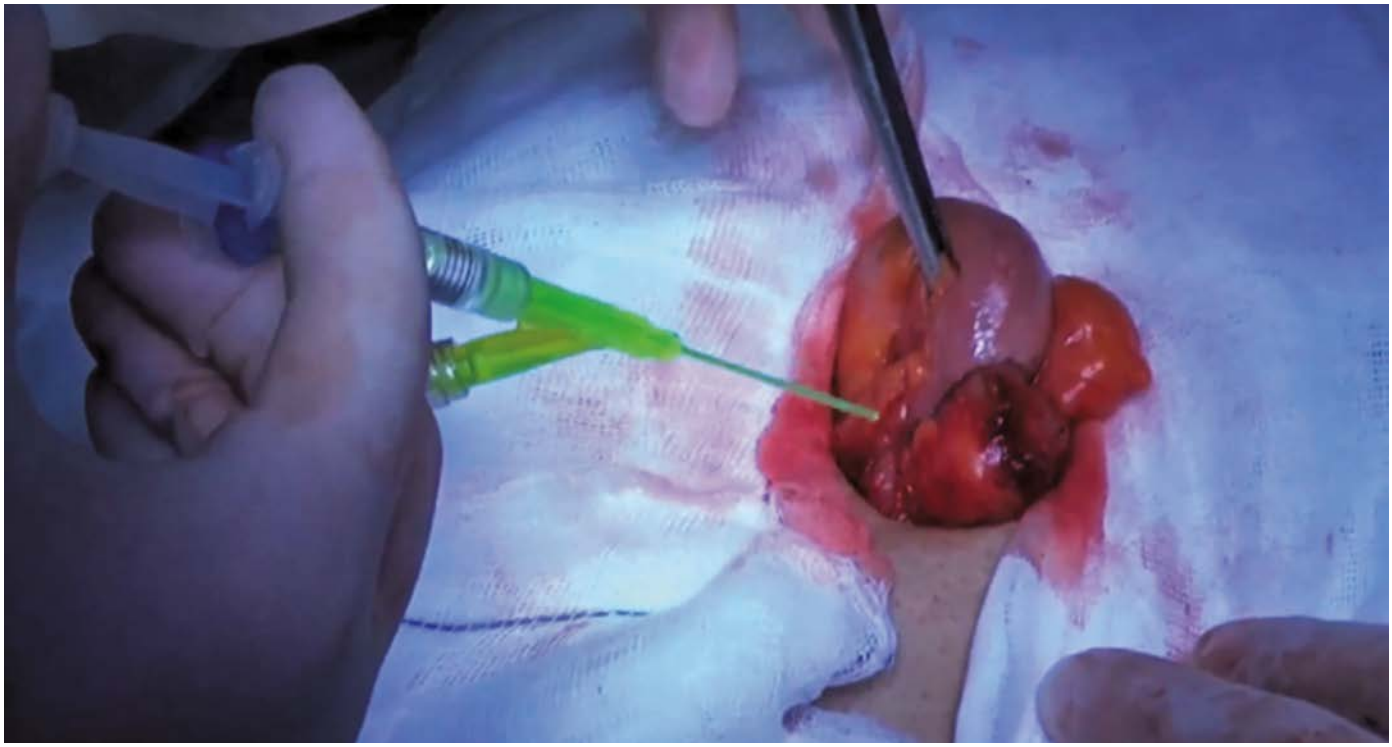

Figure 4 – *Nebulization of Glubran®2 onto a mechanical termino-lateral ileocolic anastomosis performed extracorporeally during laparoscopic right hemicolectomy*

purulent drainage of purulent or faecal material, leukocytosis, abnormal procalcitonin or PCR results, dynamic ileus). For an appropriate statistical evaluation, 390 consecutive patients need to be enrolled. The sample size was calculated assuming (on the basis of literature data) an anastomotic fistula incidence of 6.18%, a 50% reduction when applying Glubran®2 as sealant and reinforcement, and considering the use of a two-tailed binomial test assuming a significance level of 5% and a power of 80%. Although, on the basis of these hypotheses, 376 patients are needed, it was decided to increase the final number of patients to be enrolled to 390 (a 4% increase) so as to take into account any patients that might be lost to follow-up. At present, 118 patients have been enrolled; the data available thus far, still very preliminary but nevertheless suggestive of a favorable impact of Glubran®2, are the following:

- Mean age of patients, 68.9 years, with ASA III status in 47% of cases, mostly without significant malnutrition but presenting other predisposing factors, such as smoking (23%), vasculopathy (23%), diabetes (12%);
- preference for mechanical, side-to-side anastomosis (75%);
- evidence of type 3 anastomotic fistula in 3.7% of the cases (entirely in line with literature data), treated surgically.

The recruitment phase of the ANASTOSEAL trial is ongoing (7 centers actively involved). To participate, contact the Principal Investigators, Dr Paolo Delrio and Dr Daniela Rega (daniela.rega@gmail.com).

Glutack®: the laparoscopic system for the atraumatic fixing of the prosthesis in the abdominal wall surgery

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Fixing the prosthesis is an aspect of laparoscopic abdominal wall surgery that has always presented difficult choices and technical and clinical management issues: tacks versus sutures; absorbable versus non-absorbable tacks; difficulties in using the tack fixing device; prevention and control of post-operative pain. The latter is mainly related to the tacks: helical in shape, these are fixed to the muscle plane, which they penetrate by means of a "traumatic" spiral mechanism (causing painful stretching of the fibers).

However, there is now an innovative device available for atraumatic laparoscopic mesh fixation: Glutack®.

With each press/release of its trigger, this device delivers a calibrated drop of Glubran®2 from its distal end. Essentially, Glutack®, in addition to being extremely user-friendly, offers:

- a high-performance (strong) adhesive anchor with high resistance to the application of forces applied parallel to the tissue (i.e. shear strength); equal to over 9N (Newton), this is entirely equivalent to that of the current "mechanical/traumatic" fixing methods, and it is correlated with a high peel force;
- very quick preparation (< 1 min) and release of the drop of Glubran®2, resulting in immediate adhesion of the mesh to the tissue (fast). Glubran®2 is ideal for applying to the edges of the mesh; indeed, failure to properly fix the edge sections between the tacks can encourage the formation of adhesions and lead to relapses due to non-optimal "laying" of the mesh;
- carefully calibrated (0.0125 ml/drop – 12.5 mg), repeatable and precise ("punctiform") release of Glubran®2, without waste or dispersion of the adhesive in the abdomen (precise);
- versatility of use (versatile): a) depending on the mesh size and planned procedure, the device can be loaded with a quantity of Glubran®2 sufficient for at least 25, 40 or 50 drops, as indicated on the packaging and on the handle; b) the tip of the device is articulated so as to be able to reach difficult areas (for example, the pelvis); c) the tip design and the instrument's super-rigid rod facilitate the positioning of the prosthesis;
- flexibility (flexible), thanks to the articulated tip, it is possible to approach the site and deliver the drops of Glubran®2 from different angles (ranging from 0° to 90°) (Fig. 5). It is worth noting that applying tacks with non-articulated devices can be particularly challenging.

In our field experience (General Surgery Unit, "Madonna delle Grazie" Hospital, Matera), with different types

Figure 5 – *Glutack®. Device for atraumatic fixing of hernia prostheses. With each press/release of the trigger, it delivers a calibrated drop of Glubran®2, obtaining effective adhesive anchorage of hernioplasty meshes.*

of abdominal wall defect and different types of mesh, we prefer "treated" meshes (i.e. ones covered in an anti-adhesive film that favors optimal adaptation to the abdominal wall); at the same time, however, we have found Glutack® to be easy to use and a device that, without "revolutionizing" standard clinical practice as regards mesh fixation in abdominal wall surgery, nevertheless makes the process faster and safer (tending to reduce relapses, of which we have so far recorded none in our personal experience). It also performs better from the point of view of the patient, who can often be discharged on day I post-surgery. The use of "combined" fixation, a technique easily performed using Glutack® (Fig. 6), reduces the number of tacks needed and also allows the resorbable type to be used completely safely. Therefore, pending future evidence confirming secure fixation even with a minimum number of tacks or none at all, it can be said that, as a rule, the application of 40 drops of Glubran®2, which are in fact "equivalent" to the same number of metallic staples, plus at least 15 absorbable tacks (even when working on smaller meshes), reduces operation times and, above all, minimizes tack-related tissue trauma, which is the main cause of post-operative pain and, therefore, longer hospital stays.

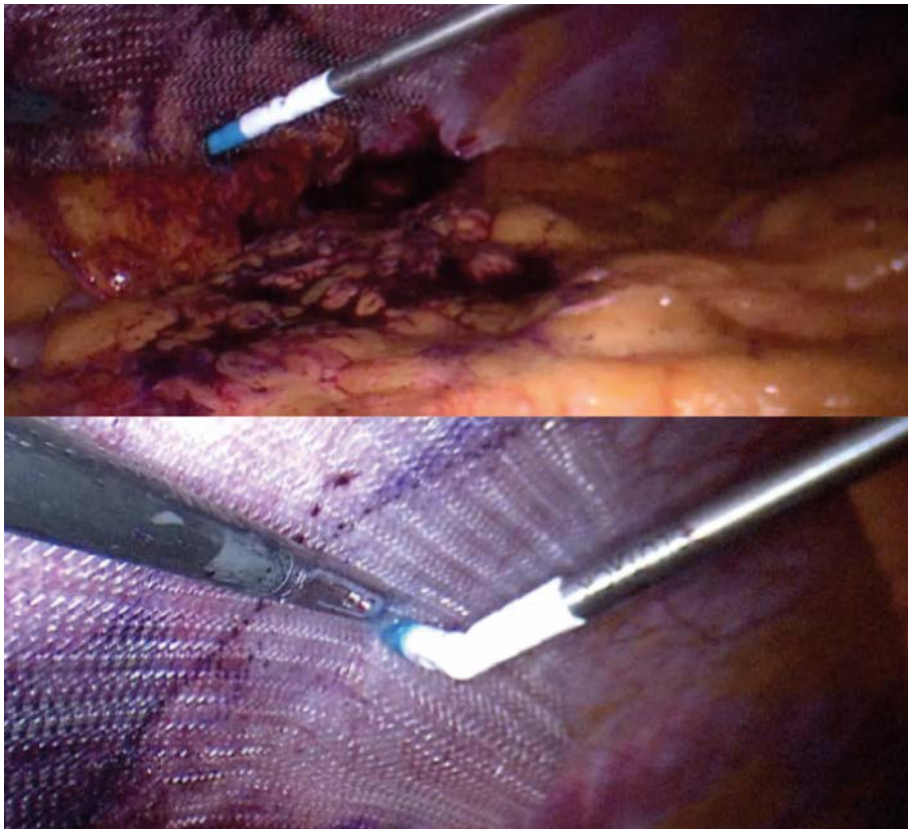

Figure 6 – *Laparoscopic repair of post-VLC trocar site hernia (right side). Use of Glutack® for "combined" mesh fixation (using Glubran®2 and tacks). The "punctiform" application of Glubran®2 means that fewer tacks are needed and the absorbable kind can be used perfectly safely.*

The Glubran®2 nebulizer for the prevention of air leaks. Preliminary data

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Prolonged air leaks are a common post-operative complication in thoracic surgery. Glubran®2 is a new synthetic tissue sealant with distinct adhesive, hemostatic and antiseptic (barrier) properties. In particular, this innovative sealant polymerizes through an exothermic reaction at low temperatures (40-45 °C), creating a thin, elastic film with high tensile strength that guarantees secure tissue adhesion; the film conforms to the anatomy of organs and tissues ("following" lung movements for example), and it is impermeable. The available evidence shows Glubran®2 to be an ideal surgical sealant: easy to use, effective, safe and inexpensive.

Glubran®2 can be used both in open thoracic surgery and in video-assisted thoracoscopic surgery (VATS), applied as an aerosolized spray to seal breaches/sections cutter in the lung parenchyma with the aim of preventing (thanks to its hemostatic/aereostatic properties) post-operative air leaks. In the past, before the advent of sealants, there was no means of preventing air leaks, and all that could be done, once they appeared, was "stabilize" them by means of various "containment" strategies, which often failed to resolve the problem (aspiration drainage, chemical pleurodesis, reoperation for surgical closure, instillation of blood through a chest tube, bronchoscopy procedures)[9].

The literature reports an initial experience with Glubran®2 which did not confirm its expected positive impact on the incidence of post-operative prolonged air leaks; however, it seems clear that the failure to demonstrate a positive effect can be attributed, in that case, to the retrospective nature of the study, the sequential-cohort design, and above all the small sample size (only 33 treated patients)[10].

Our group (Thoracic Surgery, "Tor Vergata" University, Rome) thus decided to verify the preventive potential of Glubran®2 by conducting a retrospective case-control study on an appropriate sample. We compared a group of consecutive patients submitted, from 2017, to open or thoracoscopic lung resection with application, by nebulization, of Glubran®2 (mechanical stapling of lung parenchyma, use of energy devices for lysis of pleural adhesions, careful intraoperative checking of any minimal breaches/"leaks") with a "historical" control group comprising patients undergoing the same surgery (with interrupted 3/0 silk sutures) during the 18 months prior to the introduction of the new sealant into our clinical practice. Intraoperative nebulization of the sealant was performed with the parenchyma moderately expanded (Fig. 7).

By means of a computerized procedure, the patients were then matched 1:1 for gender, age, body mass index, smoking history (positive), forced expiratory volume in the 1st second (FEV1), surgical approach (VATS *vs* open), extent of pleural adhesions (1-4) and of parenchymal resection (anatomical/typical *vs* non anatomical/atypical), and histology (benign *vs* malign). The main endpoints (with evaluation up to 3 months post-surgery) were: prolonged air leaks, thoracic drainage time, length of hospital stay and complications. For each of the comparison arms, propensity score matching selected 192 patients who were homogenous in terms of demographic and clinical variables. Briefly, the statistical analysis revealed that early post-operative air leaks were significantly less frequent in the group of patients treated with Glubran®2 (10.3% *vs* 29.1% in the controls, $p<0.0001$) and that these patients also showed shorter thoracic drainage times (1.2±0.3 *vs* 2.7±1.1 days, $p<0.0001$) with duration of air leaks reduced by about 36 hours, and shorter post-operative hospital stays (2.4±0.9 *vs* 3.8±1.7 days, $p=0.03$) (Tab.I). In our experience, the use of Glubran®2 also allowed cost savings of an average of 750 euros per patient ($p=0.01$) related to the favorable clinical outcomes that can be obtained with the sealant.

In conclusion, our experience with

Endpoints	Study group (Gubran®2) N=192	Control group N=192	P value
Immediate postoperative air leakage (incidence)	10.3%	29.1%	p<0.0001
Chest tube drainage duration (days)	1.2±0.3	2.7±1.1	p<0.0001
Hospital stay length (days)	2.4±0.9	3.8±1.7	P=0.03

Tab.I – *Results of the statistical analysis between study group and control group.*

Glubran®2 is absolutely positive, also on account of the extreme ease of use of the sealant in VATS. There are several tips and tricks that, for practical purposes, are worth listing:

- do not apply too much of the product, in other words, create a continuous but thin adhesive film (otherwise, there is a risk of the adhesive film crumbling or breaking);
- apply the sealant with the parenchyma partially expanded, keeping the tip of the nebulizer at a safe distance, about 2.5 cm;
- Glubran®2 can also be used to control any profuse bleeding, which is not easy to manage using the usual patches;
- "fix" the right middle lobe to the adjacent residual parenchyma, especially if it is particularly mobile; this will prevent it from twisting post-operatively;
- bear in mind the possibility of thick pleural adhesions in the event of reoperation; these can make it very difficult to isolate the hilum.

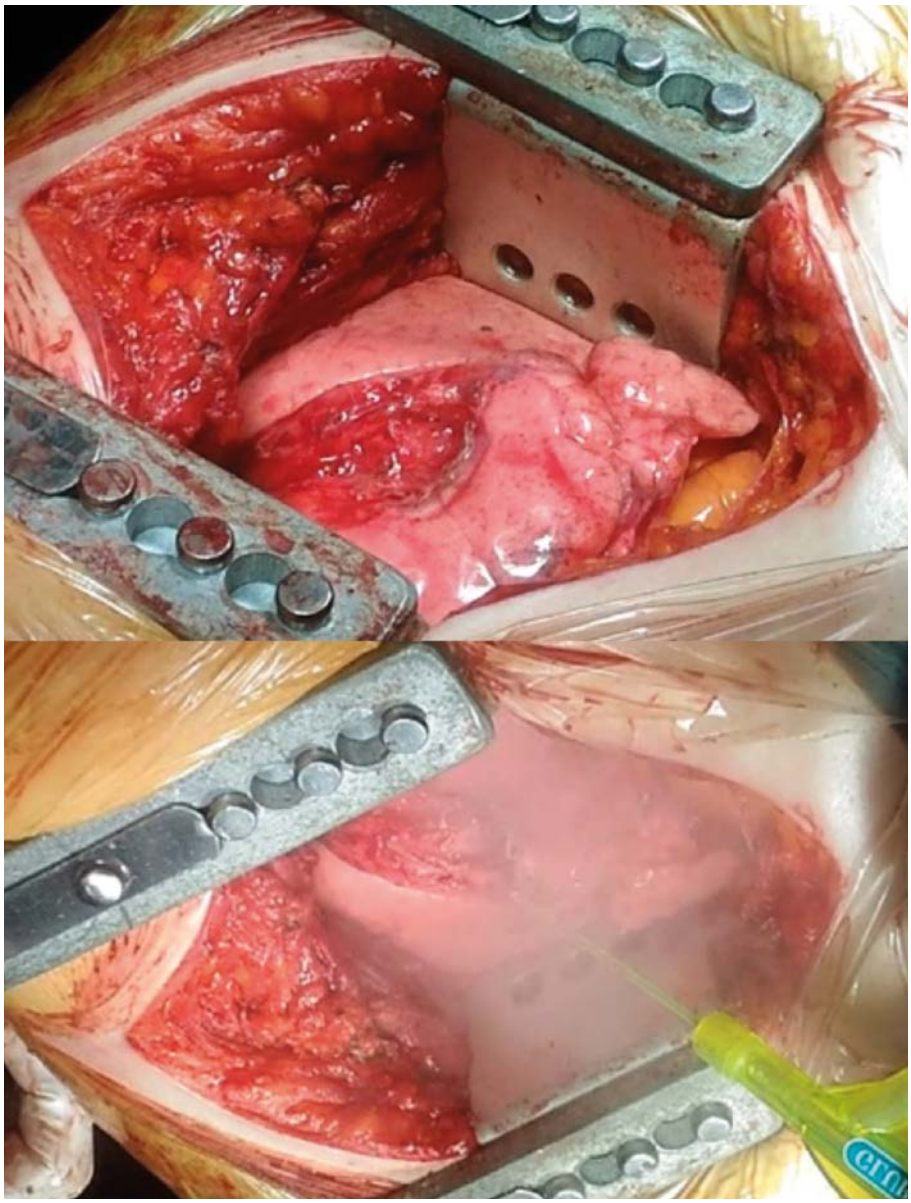

Figure 7 – *Lung surgery. Application by nebulization of Glubran®2 with moderately expanded parenchyma.*

Glutack® in robotic surgery: atraumatic fixing in the repair of ventral hernias

Christian Galatioto
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As in other fields, the advent of minimally invasive laparoscopic surgery and, in recent years, robotic surgery has represented a true revolution in abdominal wall defect repair, and has determined a drastic reduction in the incidence of the most feared postoperative complication, the surgical site infection (SSI - 4-5% open vs 1.4% lap); this data has been confirmed by all the main international guidelines.
The laparoscopic approach can potentially be used in all the different abdominal wall repair methods and techniques: the use of intra-peritoneal onlay mesh (IPOM) with/without hernia defect closure; transabdominal preperitoneal repair (TAPP); totally extraperitoneal repair (TEP); trans-abdominal retromuscular repair (TARM), and transversus abdominis muscle release (TAR) in more complex surgical cases.
However, laparascopic IPOM (L-IPOM) is the technique used in the vast majority of cases and it involves positioning, intraperitoneally, a bicomponent, anti-adhesive mesh. This would "traditionally" be fixed using a variable number of staples and tacks, which are the main cause of post-operative pain. The other techniques are more complex to perform laparoscopically. The robotic platform, on the other hand, allows, in particular, easier dissection between muscle planes, reconstruction of the abdominal wall, and (as in open surgery) retromuscular positioning of the mesh, which is more correct. Indeed, it avoids intraperitoneal placement (where the prosthesis is in contact with the abdominal viscera), which in over 50% of cases leads to the appearance of adhesions. In other words, robotic platform allows easy and "physiological" abdominal wall reconstruction (AWR), while also reducing or eliminating the use of fixation devices, which cause post-operative pain; furthermore, if a double console is available, other surgeons can easily be instructed in the use of the technique. In our experience (Emergency Surgery Unit, New Santa Chiara Hospital, University of Pisa, Italy), the advantage of using a robot (as opposed to performing open or laparoscopic surgery) emerges particularly in relatively more complex cases, such as voluminous laparoceles or reoperations for recurrence. The case presented here is an example: it concerns a patient with an umbilical hernia previously treated in open surgery with a preperitoneal mesh, complicated by diastasis recti and repaired with the "sublay" technique (retromuscular repair with self-gripping mesh).
An interesting and promising alternative to the use of self-gripping mesh is Glutack®, which allows calibrated and "punctiform" application of drops of Glubran®2 in order to obtain firm atraumatic fixing of the prosthesis (Fig. 8). Glutack® eliminates the need for tacks and therefore markedly reduces post-operative pain. This translates into a significant improvement in the patient's short-term quality of life.

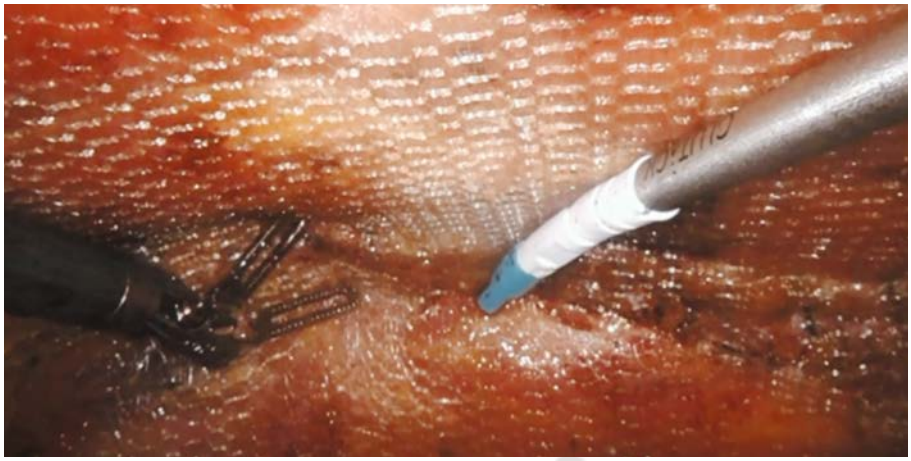

Figure 8 – *Robotic repair of recurrent umbilical hernia. Glutack® is used to obtain atraumatic retromuscular fixing of Prolene mesh. Furthermore, since Prolene is not a bicomponent product, the calibrated drops of Glubran®2 can easily be applied through the mesh.*

The application of nebulized Glubran®2 in breast surgery. Preliminary results of the Glubreast trial

Emanuela Esposito
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Post-operative seroma is the most frequent complication of axillary lymph node dissection in women with breast cancer. Its pathogenesis is complex and variable. Preventing its onset can reduce the risk of infection at the surgical site, reduce outpatient visits for repeated aspirations of serum, and therefore reduce hospital costs; it can also avoid delayed initiation of adjuvant therapies. Glubran®2 is a biocompatible synthetic sealant, CE approved for internal human uses and surgical procedures. The innovative product forms a sealing film in the operative field, occluding lymphatic leaks and limiting the formation of lymphorrhea.

In May 2018 our group (Breast Cancer Surgery Unit, National Cancer Institute, IRCCS "Fondazione G. Pascale", Naples, Italy) launched the Glubreast trial (Principal Investigator: Dr Raimondo Di Giacomo), a phase III randomized prospective study aiming to verify the effectiveness of Glubran®2 in preventing/reducing seroma formation after axillary lymph node dissection in patients undergoing conservative breast surgery or modified radical mastectomy. In order to eliminate selection *bias* in the study, a randomization software was used to assign the patients to the respective arms (experimental arm and control arm).

The experimental arm comprises patients undergoing conservative surgery or mastectomy associated with axillary lymph node dissection followed by intraoperative application of 1 ml of nebulized modified cyanoacrylate sealant, in accordance with the Standard Operating Procedures (Fig. 9); the control arm comprises women undergoing the same surgical procedures without application of the sealant.

The inclusion criteria are: women aged >18 years, a confirmed diagnosis of invasive breast cancer, planned axillary lymph node dissection on the basis of the presence of clinically palpable and/or positive lymph nodes (quadrantectomy /modified radical mastectomy). To improve the homogeneity of the sample, women receiving neoadjuvant therapies, those with a history of radiation therapy on the chest wall, and candidates for breast reconstruction are excluded.

It is envisaged that 220 patients (110 per arm) will be enrolled in the study in order to achieve a statistical power of 80% in approximately 48 months. The Glubreast trial is being conducted in accordance with the Good Clinical Practice (GCP) criteria, with safety reporting procedures, quarterly internal audits and monitoring by the institutional scientific committee. The main endpoint is reduction of the total volume of serum (ml) on day 15 post surgery. Secondary endpoints are: the number of needle aspirations needed after drain removal, the correlation of sealant effectiveness with body mass index (BMI), and the occurrence of adverse events.

Of the patients thus far enrolled, 66 have completed the follow-up. The preliminary results, albeit referring to a limited sample, are encouraging, showing that the patients in the experimental arm have their axillary drain removed 3 days earlier than those in the control arm. Furthermore, an analysis by subgroups showed that the effectiveness of Glubran®2 increases in direct proportion to the single patient's BMI. The fact that no adverse events occurred and no cases of hematoma or infection at the surgical site were recorded indirectly confirms the hemostatic and bacteriostatic effects of Glubran®2.

Most data available in the literature come from non-randomized studies that do not offer a level of evidence sufficient to guide daily clinical practice and improve surgical outcomes in women with breast cancer. Glubreast is the first randomized trial conducted with the aim of evaluating the effectiveness of Glubran®2 in reducing post-operative lymphorrhea/seroma in breast surgery.

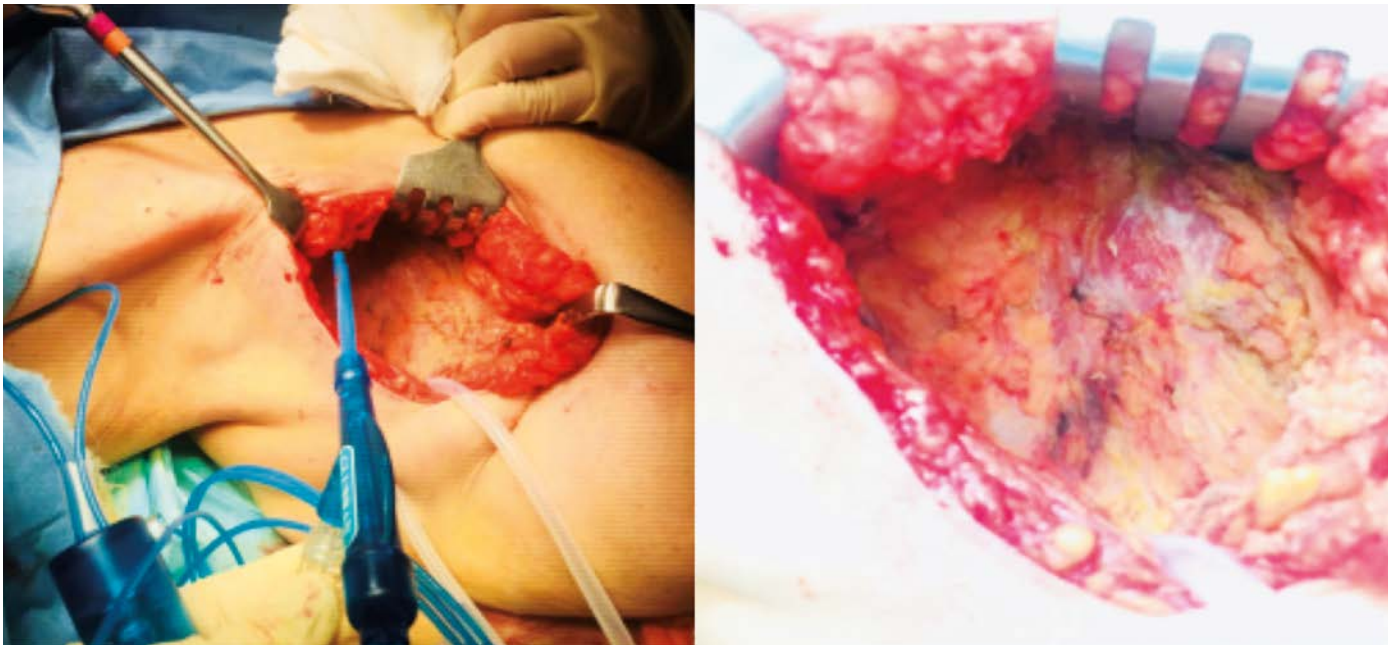

Figure 9 – *The Glubreast study. Axillary lymph node dissection in breast cancer, with application of nebulized Glubran®2.*

Rutilight®

Michela Giannecchini
Research and Development - GEM Srl - Viareggio, Italy

If we were to ask a surgeon to name one of the main difficulties routinely encountered in open surgery, the reply would quite probably be "illuminating the surgical field properly". Rutilight® has been designed to solve this particular problem. Rutilight® is a medical device, unique on the market, that directly illuminates the surgical field in a convenient and practical way, since it is actually fitted to surgical instruments. It is a lightweight and handy disposable sterile silicone ring made up of 12 LEDs (100,000 lumens), adaptable to any surgical instrument with a diameter of between 5 and 8 mm (electro-cauterizers, Yankauer aspiration tubes, clamps, needle holders, coagulators, etc.).
Since it emits light immediately behind the operational/functional part of the instrument, there are no shadows. Rutilight® allows better intervention/repair, decreasing the rate of complications, bleeding and hemorrhage episodes, which are frequently associated with the lack of a good view of the operating field. In fact, it improves the accuracy and precision of the surgical maneuvers, allowing a better final result; it enhances the surgeon's dexterity, and reduces operation times and post-intervention risks for the patient. Rutilight® delivers up to 5 hours of intense cold light that does not distort the natural color of organs, vessels and tissues. Up to three luminous rings can be connected simultaneously during the same operation.
The Rutilight® device has been tested by Dr Raimondo Di Giacomo and the team at the Breast Cancer Surgery Unit, National Cancer Institute, IRCCS "Fondazione G. Pascale", Naples (Italy). Their experience has led to the following indications:

1) Conservative (nipple- and skin-sparing) mastectomies. In this case, Rutilight® makes it possible to work with a skin incision of 4-4.5 cm and, through this incision, to easily prepare the pocket, between the pectoralis muscles, for the prosthetic implant; exploiting the transillumination effect created by the light source of the device itself, it also allows the thickness and integrity of the flap to be evaluated.
2) Dissection of particularly deep axillae. Rutilight® guarantees more accurate and complete illumination ensuring correct visualization of nerves and vessels (Fig. 10).

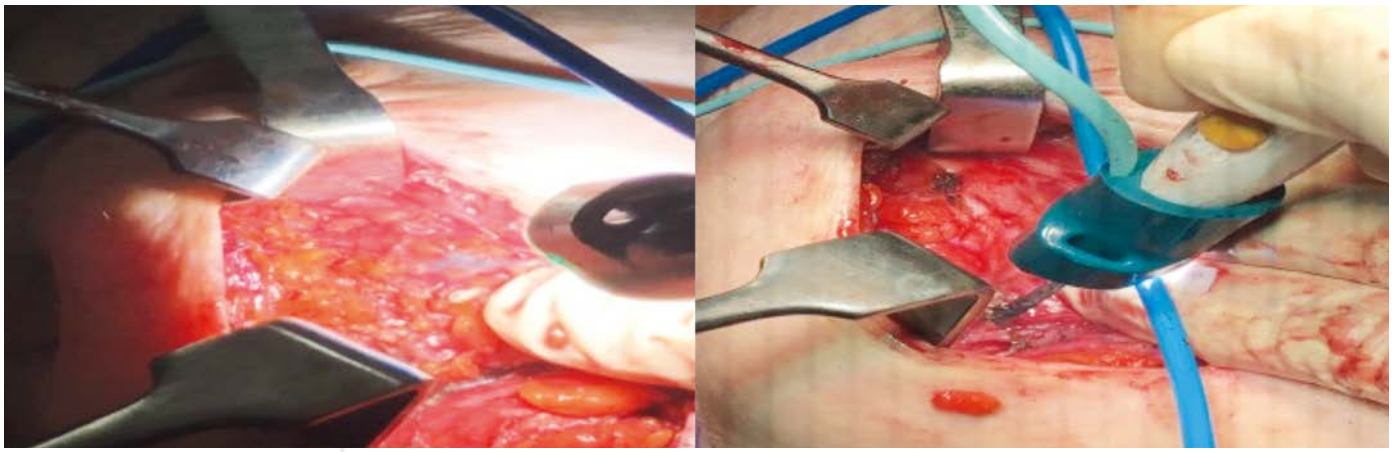

Figure 10 – *Use of Rutilight® in conservative skin-sparing mastectomy with breast reconstruction and axillary lymph node dissection. The innovative device allows targeted illumination of the deeper areas of the operating field (courtesy of Dr. Raimondo Di Giacomo, Breast Cancer Surgery Unit, National Cancer Institute, IRCCS "Fondazione G. Pascale", Naples - Italy).*

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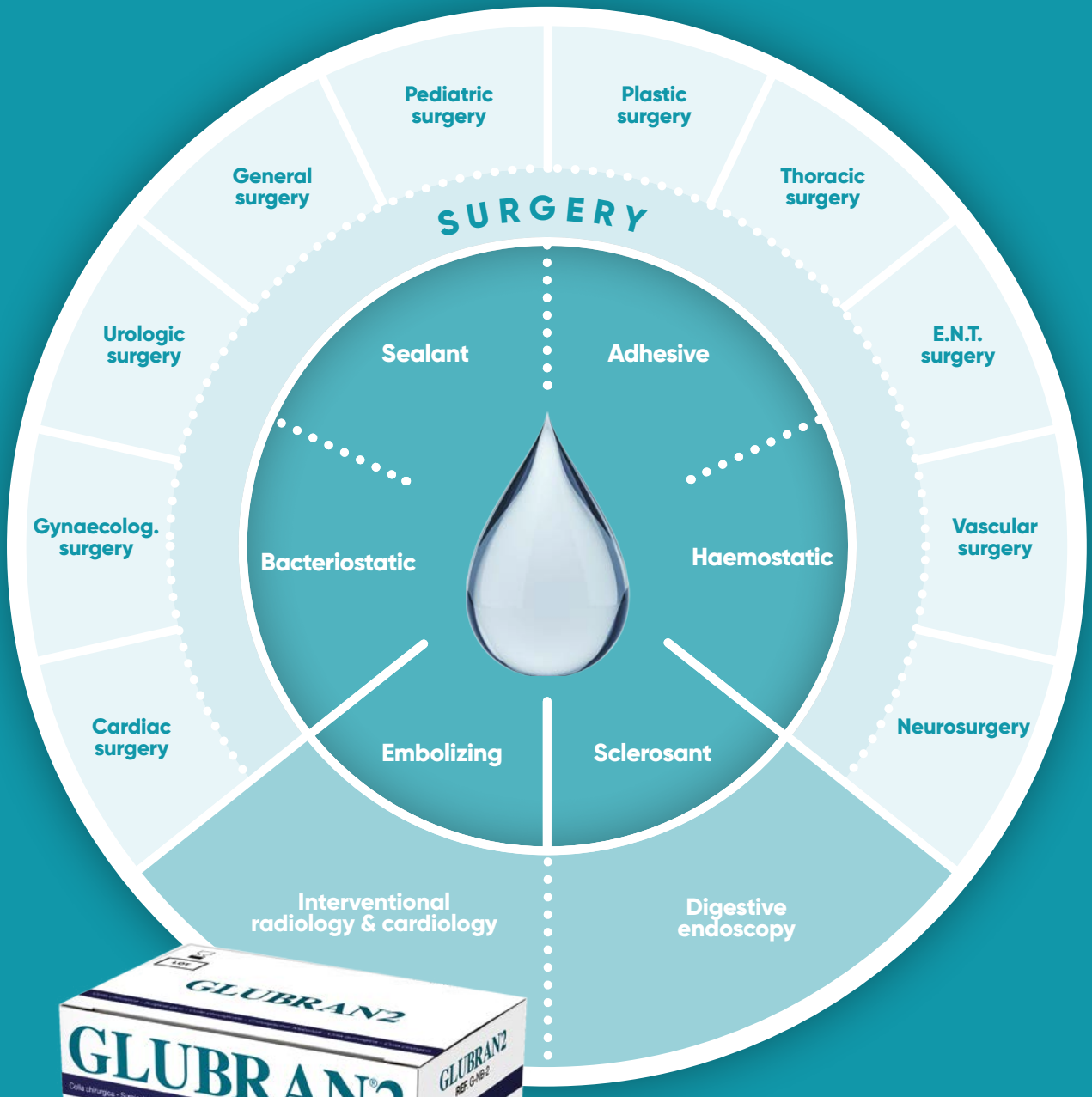

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