Assut sutures of Switzerland

Summary of Safety and Clinical Performance (SSCP)

Absorbable Surgical suture

AssuCryl® Lactin

CE-Mark since 2006

VERSION 06

21.07.2025

Assut Medical Sàrl
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Table of abbreviations

FSCA	Field Safety Corrective Actions
MDD	Medical Device Directive
MDR	Medical Device Regulation
CE-marking	European Conformity - a certification mark that indicates conformity with European Union (EU) standards
EUDAMED	European Database on Medical Devices
Class IIa and IIb	Classification of Medical Devices, IIa and IIb are low and medium risks devices
NB	Notified Body
PMCF	Post Market Clinical Follow-up
SSCP	Summary of Safety and Clinical Performance
MDCG	*Medical Device Coordination Group*
EN ISO	European Norm International Organization for Standardization
Ph. Eur.	European Pharmacopeia
CS	Common Specification
USP	United State Pharmacopeia
CAPA	Corrective Action Preventive Action
PGLA	Polyglycolic-co-L-Lactide (PGLA)
O.R.	Operating Room

Revision history

Version number	Date issued	Change description	Validated by Notified Body
00	25.08.2021	Initial revision	☐ **YES** **Validation language: English** ☐ **NO** (Only applicable for class IIa and some IIb implantable devices for which the SSCP is not yet validated)
01	13.06.2022	Update according to the comments of DEKRA, TDR01/Q23, update of the table of content related to MCDG 2019-1	☐ **YES** ☐ **NO**
02	30.11.2022	Update according to the comments of DEKRA, TDR01/Q23, see red	☐ **YES** ☐ **NO**
03	12.12.2022	Update according to the comments of DEKRA, TDR05/Q53, see red chapter 6.6.	☐ **YES** ☐ **NO**
04	24.02.2023	Update according to the comments of DEKRA, TDR05/Q53 (cancellation of equivalent device §6.1.2 and perfection of the clinical data §6.3)	☐ **YES** ☐ **NO**
05	20.05.2025	General review and update with new standards	☐ **YES** ☐ **NO**
06	2.07.2025	EMDN description corrections	☐ **YES** **Validation language: English** ☐ **NO** (Only applicable for class IIa and some IIb implantable devices for which the SSCP is not yet validated)

Approval:

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Name:	Barbara Kathage	Catherine Baerfuss	Marc Baerfuss
Date:	21.07.2025	21.07.2025	21.07.2025
Signature:			

Table of Contents

1 Introduction

This summary of safety and clinical performance (SSCP)for the surgical absorbable suture AssuCryl® Lactin manufactured by Assut Medical Sàrl shall meet the requirements of the Medical Device Regulation (EU) 2017/745 intended to fulfil the objectives of the MDR to enhance transparency and provide adequate access to information. The manufacturer shall draw up a SSCP for implantable devices and for class III devices (higher risk class, implantable devices), other than custom-made or investigational devices. The SSCP contains summarized information from the Post Market Surveillance System, Clinical Evaluations, Risk Management and Technical Documentation that are relevant for the end user, healthcare professional or patient.

The SSCP shall be validated by a notified body (NB) and made available to the public via the European database on medical devices (Eudamed). The SSCP is intended to provide public access to an updated summary of clinical data and other information about the safety and clinical performance of the medical device.

This SSCP is written according to article 32 of the MDR (EU) 2017/745 and in a way that is clear to the intended user.

The SSCP is also adapted in a readable format for lay persons. A usability test has been performed in order to identify the non-readable/understanding parts. The findings are implemented in this revision of document.

The readable format excludes the italics part of the chapters 6.1, 6.1.1, 6.3.1 and 6,3.2, which are focused on technical information dedicated to end-users.

The content of this SSCP report is reviewed annually in line with the Post-Market Surveillance Activities but updated only if any change in the benefit-risk ratio is to be expected from these activities or any other sources like recalls, FSCAs for example or at least every five years.

For further information, it is possible to write to regulatory(at)assutsutures.com.

2 Device identification and general information

2.1 General information

Device trade name	AssuCryl® Lactin
Manufacturer name and address	Assut Medical Sàrl PO Box No. 5 Av. de Rochettaz 57 CH-1009 Pully Switzerland
Manufacturer single registration number (SRN)	CH-MF-000009358
Basic UDI-DI	07613406ACLLPGLAHT
Class of the device	Class 3, Rule 8, Annex VIII, MDR
Year when the device was first CE-marked	2006
Authorised representative (name, address, SRN)	MT Promedt Consulting GmbH Ernst-Heckel-Strasse 7 66386 St-Ingbert Germany **SRN : DE-AR-000000085**
NB's name **NB's single identification number**	DEKRA Certification B.V. Meander 1051 6825 MJ Arnhem The Netherlands ID no. CE 0344

Medical Device nomenclature (EMDN)	**Code :** H0101010202 POLYGLYCOLIC WITH LACTIC ACID MULTIFILAMENT

3 Intended use of the device

3.1 Intended purpose/intended use and indications/application

AssuCryl® Lactin braided sutures are intended for use in general soft tissue approximation and/or ligation, including use in ophthalmic surgery but not in cardiovascular surgery, microsurgery and neural tissue.
AssuCryl® Lactin is suitable for every patient who complies with the intended purpose.
The suture material to be used is selected in accordance with the patient's condition, the surgeon's experience, the surgical procedure and the size of the wound.

3.2 Contraindications

AssuCryl® Lactin braided sutures, being absorbable, should not be used where long-term stability of the suture material is required and should not be used in cardiovascular surgery, microsurgery or neural tissue.

4 Device Description

4.1 Device description

AssuCryl® Lactin is a braided synthetic absorbable suture prepared from a copolymer of glycolide and L-Lactide 90:10 (Glacomer 91) made of ≥ 94.8% of polyglycolide-co-L-Lactide, ≤ 5% from copolymer of glycolide and L-lactide 30:70 (Glacomer 37) and calcium stearate and ≤ 0.2% of dye for the violet colour.
AssuCryl® Lactin is non-antigenic (do not cause an immune system response) and non-pyrogenic (do not cause heat or fever when implanted into the body).
AssuCryl® Lactin is available in different diameters and lengths with high-quality stainless steel needles in various types and lengths, or without needles. Refer to the catalogue for details. The needle is removed when the thread is in place.
AssuCryl® Lactin meets all requirements established by the United States Pharmacopeia (USP) for absorbable surgical sutures and the European Pharmacopeia (Ph. Eur) for synthetic braided absorbable sterile sutures, current editions.

Once AssuCryl® Lactin has been implanted there may be a faint reaction to a foreign body with a moderate initial inflammatory reaction, which is followed by a gradual encapsulation of the suture by fibrous connective tissue. Progressive loss of tensile strength and absorption of AssuCryl® Lactin will occur by means of hydrolysis.
Implantation studies indicate that the AssuCryl® Lactin braided suture material retains approximately 75% of its initial tensile strength after 14 days and approximatively 50% after about 21 days. Absorption begins as a loss of tensile strength followed by loss of mass and is essentially complete between 56 to 70 days.
The sutures should be prepared in the order in which the surgeon will use them. The O.R. assistant opens the aluminum foil at the symbol “Open here” and passes the inside suture Tyvek® envelope to the sterile area by flipping it into the basin/sterile table with no contact with liquids. The scrub nurse unseals the Tyvek® envelope to reach the suture (with or without needle) from its wrapper with sterile gloved hands or a sterile instrument. Work over the sterile field to avoid contaminating the suture.

4.2 Previous generation(s) or variants

Previous generation(s) or variants of the device in question do not exist.

4.3 Description of accessories and other devices

No special accessories are intended by the manufacturer to be used in combination with the device

4.4 Description of any other devices and products which are intended to be used in combination with the device

No devices or products are intended to be used in combination with AssuCryl® Lactin

5 Risks and warnings

ASSUT Medical Sàrl has defined policy, roles, responsibilities and the methods for performing a risk management process for the manufacturing of the product category "Synthetic Sterile Absorbable Surgical Sutures". The risk management plan describes the risk management activities carried out in accordance with the requirements of MDR (EU) 2017/745, ISO 14971:2019 and ISO TR 24971:2020. The risk management is updated every time it is necessary and at least once a year as part of the Post Market Surveillance. The aim of those reviews is to monitor realization of FMEA (Failure Modes and Effects Analysis) Table mitigation action plans and to guaranty new risk integration. Depending on the risks to address, every process responsible and Risk Identification Form authors can participate to Risk Reviews. After Risk Reviews, if FMEA Table has been modified, the Risk Management File has to be updated. In case of Technical File revision, the FMEA Table and the Risk Management File can be verified and updated if necessary. The used monitoring system synthetizes and shares a risk status into annual Management Review.
Previous and actual data that are used to determine risks and warnings are derived from PMS activities, Clinical evaluation report, Risk management report and biocompatibility.

5.1 Residual risks and undesirable effects

Undesirable reactions associated with the use of this suture material include transitory local irritation around the wound site, inflammatory foreign body reaction, erythema and induration during the process of absorption in subcuticular sutures.
Poly lactic acid degrades to form lactic acid which is normally present in the body. This acid then enters tricarboxylic acid cycle and is excreted as water and carbon dioxide. No significant amounts of accumulation of degradation products of PGLA have been reported in any of the vital organs. For further information please contact the manufacturer. Other interactions with other devices, medicinal products and other substances are not known.

5.2 Warnings and precautions

The intended users are healthcare professionals, as the user should be familiar with the surgical procedures for which the suture material is used before applying AssuCryl® Lactin for wound closure, as the risk of wound dehiscence can vary depending on where the wound is located and what suture material is used. As with any foreign body, contact over a longer period of the suture material with

saline solutions can lead to the formation of concretions (urinary tracts, bile ducts). Contaminated wounds should be surgically tended accordingly.

When closing wounds that are under stress or are stretched or require further support, the surgeon ought to use further non-absorbable suture material as and when appropriate. Adequate knot security requires the standard surgical technique of flat and square ties with additional throws as indicated by surgical circumstances and experience of the surgeon.

Skin sutures which must remain in place more than 7 days may cause localized irritation and should be snipped off or removed as indicated. Under some circumstances and notably orthopedic procedures, immobilization by external support may be employed at the discretion of the surgeon. In case of poor blood supply in the tissues, consideration should be given to delayed absorption time. This material may be inappropriate in elderly or malnourished or debilitated patients or in patients whose wounds heal slowly.

When using AssuCryl® Lactin - or any other suture material – the surgeon must make sure not to damage the thread; in particular, the thread must not be crushed or squeezed by surgical instruments such as forceps or needle holders. To prevent the needle being damaged during handling it should always be held in the area about 1/3 to 1/2 of its length from the attached end. Holding the needle in the area of the point can impair the penetration performance and even break the needle. Holding the attached end can make it bend and even break. If needles are mishandled to alter the shape, they can lose resistance to stability and bending ability. If a needle starts to bend, the user should immediately stop using the needle and take another suture. Re-bending is totally forbidden since it can lead to a needle breakage. When handling surgical needles, particular care must be taken to avoid inadvertent stick injury. All needles are magnetizable and should therefore not be used in an active magnetic field.

Never re-use a suture to avoid risks of contamination. If any serious accidents occur in relation to the use of this device, immediately report it to the device manufacturer and the competent Authority.

5.3 Summary of FSCA (Field Safety Correction Action)

According to the Post market Surveillance plan the FSCA are monitored as soon as there is an alert and this summary will be updated in the course of the FSCA.

In 2022, there was one FSCA for the product category AssuCryl Lactin (PGLA), Model Numbers/REF: L40036 resp. L40034. Neither other alerts, incidents serious and non-serious, adverse reactions, withdrawals were identified.

Assut Medical was informed about a complaint related to a mix-up of two lots, which resulted in an incorrect indication of the diameter of the suture material. The lots have been only sold to 1 country with no clinical consequence to expect for the patients. Only the 2 mentioned references were affected.

No patient has been harmed or injured.

6 Summary of Clinical evaluation and post-market clinical follow-up

6.1 Clinical Background of the device or similar

For over a century, sutures have been almost exclusively used for wound closure and remain the largest group of biomaterials used for surgical operations. Since the first introduction of synthetic, bio-absorbable polymers in the 1970s, they have found successful application as suturing materials. Polyglactin was the second synthetic absorbable suture to become available on the market after polyglycolic acid. It is a coated, braided, multifilament suture like polyglycolic acid. Polyglactin 910 consists of a copolymer made from 90% glycolide and 10% l-lactide. This suture has similar handling properties to polyglycolic acid but has more tensile strength (34).

After an injury or surgery, a surgical suture is used to hold tissues together. A suture consists of a needle with a length of thread attached. The optima suture should be easy to handle and have high tensile strength and knot security. It should cause minimal tissue reaction, and its material should resist infection and have good elasticity and plasticity in order to accommodate wound swelling. However, there is no single suture that can fulfil these criteria. Therefore, a surgeon must choose suture material based on type of surgery that she or he is performing because different tissues have different requirements for suture support (some need only a few days, e.g. muscle, subcutaneous tissue, and skin, while others require weeks or even months, e.g. fascia and tendons). In addition, the healing rates of tissues differ depending on factors such as infections, debility, respiratory problems, obesity, collagen disorders, malnutrition, malignancy, and drugs (1).
The goals of wound closure include obliteration of dead space, even distribution of tension along deep suture lines, and maintenance of tensile strength across the wound until tissue tensile strength is adequate (2).

Absorbable sutures are divided into the man-made fibers e.g. polyglycolic acid and polydiaxone, and the natural fibers, e.g. catgut. In terms of physical configuration, the suture material can be classified into monofilament and multifilament forms. Multifilament suture comes in twisted and braided forms. Braided sutures tend to be easiest to handle and tie, but they also have the potential to sequester bacteria between the strands, resulting in increased risk of infection.

Sutures are classified according to the number of strands of which they are comprised. Monofilament sutures are made of a single strand of material. Because of their simplified structure, they encounter less resistance as they pass through tissue than multifilament suture material. They also resist harboring organisms that may cause infection. These characteristics make monofilament sutures well suited to vascular surgery. Monofilament sutures tie down easily. However, because of their construction, extreme care must be taken when handling and tying these sutures. Crushing or crimping of this suture type can nick or create a weak spot in the strand. This may result in suture breakage.

Multifilament sutures consist of several filaments, or strands, twisted or braided together. This affords greater tensile strength, pliability, and flexibility. Multifilament sutures may also be coated to help them pass relatively smoothly through tissue and enhance handling characteristics. Coated multifilament sutures are well suited to intestinal procedures (3).

Suture materials are frequently coated, especially braided or twisted sutures, to facilitate their handling properties, particularly a reduction in tissue drag when passing through the needle tract and the ease of sliding knots down the suture during knotting. Absorbable coatings include Poloxamer 188 and calcium stearate with a copolymer of glycolic acid (GA) and lactic acid (LA). The trend is toward a coating material that has a chemical property similar to the suture to be used (4).

The implantation of biomaterials initiates both an inflammatory reaction to injury as well as processes to induce healing. The healing of wounds is a complex dynamic process that can be separated into a series of phases. Phase I of wound healing involves an inflammatory response over 1–5 days that induces an outpouring of tissue fluids into the wound, an increased blood supply and cellular and fibroblast proliferation. In Phase II of wound healing, covering a period of 5–14 days, there is an increased collagen formation and deposition within the wound, together with formation of fibrin and fibronectin through fibroblastic activity, and wound closure/contraction commences.

Phase II gradually merges to Phase III, from day 14 onward, and there is reorganization and maturation (cross-linking) of collagen fibers together with deposition of fibrous connective tissue, the latter resulting in scar formation. This healing process occurs when there is no infection, minimal edema (swelling), or fluid discharge. Complications in would healing and their attendant delays commonly result from two primary causes, infection and mechanical effects (4).

Necessary for the placement of sutures in tissue, surgical needles must be designed to carry suture material through tissue with minimal trauma. They must be sharp enough to penetrate tissue with minimal resistance. They should be rigid enough to resist bending, yet flexible enough to bend before breaking. They must be sterile and corrosion-resistant to prevent introduction of microorganisms or foreign bodies into the wound. Comfort with needle security in the needle holder, the ease of passage through tissue, and the degree of trauma that it causes all have an impact upon the overall results of surgical needle performance. This is especially true when precise cosmetic results are desired.

6.1.1 Degradation of absorbable surgical sutures (PGLA)

Different degradation mechanisms are described in literature such as hydrolysis and oxidative, cellular and bacterial degradation. The parameters that control the hydrolysis rates are the temperature, molecular structure, and ester group density as well as the species of enzyme used. The degree of crystallinity may be a crucial factor, since enzymes attack mainly the amorphous domains of a polymer.

Poly lactic acid degrades to form lactic acid which is normally present in the body. This acid then enters tricarboxylic acid cycle and is excreted as water and carbon dioxide. No significant amounts of accumulation of degradation products of PLA have been reported in any of the vital organs. It is also reported that in addition to hydrolysis PGA is also broken down by certain enzymes, especially those with esterase activity. Glycolic acid also can be excreted by urine (5).

It is important to note that there is not a linear relationship between the copolymer composition ant the mechanical and degradation properties of the materials. For example, a copolymer of 50% glycolide and 50% DL-Lactide degrades faster than either homopolymer. Copolymers of L-lactide with 25-70% glycolide are amorphous due to the disruption of the regularity of the polymer chain by the other monomer. A copolymer of 90% glycolide and 10 % L-lactide was developed as an absorbable suture material. It absorbs within 3-4 months but has a slightly longer strength-retention time (6).

PGLA suture elicits a minimal acute inflammatory reaction in tissue and ingrowth of fibrous connective tissue (7). Progressive loss of tensile strength and eventual absorption of PGLA suture occurs by means of hydrolysis, where the copolymer degrades to glycolic and lactic acids, which are subsequently absorbed and metabolized in the body (4). There were strong indications from the studies performed by Salthouse et al. (8), that the products of suture hydrolysis are probably metabolized through the oxidative enzyme systems of cells adjacent to the suture.

The degradation of PLA, PGA and PLA/PGA copolymers generally involves random hydrolysis of their ester bonds. PGLA degradation is mainly based on hydrolysis (9). The rate of degradation in biological tissue is defined by the "half-life tensile strength". PGLA is a material with a relative fast absorption rate. It retains the original strength for 75% after 2 weeks, and the substantially complete absorptions is after 8-10 weeks (IFU Vicryl, 2).

The rate of degradation however is determined by factors such as configurationally structure, copolymer ratio, crystallinity, molecular weight, morphology, stresses, and amount of residual monomer, porosity and site of implantation. This explains the difference in findings for the degradation in clinical investigations.

Product made from PGLA has been used widely as a biocompatible and biodegradable material for tissue engineering (4). Summarizing literature articles describe the excellent biocompatibility and product safety (8) of the PGLA based surgical sutures. The advantage of the material is that neither the polymer nor its degradation products glycolic acid and lactic acid are toxic when implanted in vivo (4).

6.2 Clinical evidence for the CE-marking

No clinical investigations have been conducted before the CE-marking of AssuCryl® Lactin.

6.3 Summary of clinical data from other sources

PGLA sutures are multifilament braided sutures introduced in the 1974. Since its invention PGLA based synthetic absorbable sutures are widely used around the world where temporary support for tissue approximation is required. Apart of pre-clinical data generated for the purpose of CE certification under MDD 93/42/EEC and as AssuCryl® Lactin is a legacy device which is on the market since since 2006, clinical experiences and clinical data were collected regularly within the post-market surveillance activities are available on the devices.

6.3.1 Application

Application of PGLA in general soft tissue approximation and/or ligation

In the following results of different studies that are summarized, that provide information on polyglactin 910 (PGLA) in clinical use.

Several investigations were performed in order to compare the performance of different absorbable surgical suture materials (see table 1). The differences in the absorption time are described in the following figure 1 which is referenced by Pillai (1).

Suture material	Type	Commercial name	Tensile strength loss	Absorption time (days)
Plain catgut	Natural fiber	Plain catgut	Variable up to 7 days, as long as 10 days	70
Polyglytone	Monofilament	Caprosyn™	50–60% at 5 days, 20–30% at 10 days	56
Chromic catgut	Natural fiber	Chromic catgut	Variable up to 14 days, as long as 21 days	More than 90
Polyglactin 910	Braided	Vicryl™	75% at 14 days, 50% at 21 days	56–70
Glycomer 631	Monofilament	Biosyn™	75% at 14 days, 40% at 21 days	90–110
Poliglecaprone	Monofilament	Monocryl™	50–70% at 7 days, 20–40% at 14 days	91–119
Polyglycolic acid	Braided	Dexon™	60% at 7 days, 20% at 15 days	90–120
Polyglycolic acid	Monofilament	Maxon™	75% at 14 days, 65% at 21 days	120–180
Polydioxanone	Monofilament	PDS II®	More than 85% at 14 days, 60% at 28 days	120–180

Figure 1: *Absorption times of absorbable surgical sutures (Pillai and Sharma, 2010 [1])*

Table 1*: Summary of results of different clinical studies, trials and investigations regarding the use of PGLA in general soft tissue approximation and/or ligation. If the studies refer to the use of a specific PGLA suture, the brand name is mentioned, even if these are not equivalent devices but only similar devices.*

Reference	***Content***
Ishikawa et al. (10)	*Polyglactin 910 was less likely to form adhesions in the peritoneal cavity of rats compared to silk, Polydioxanone and Poliglecaprone 25.*
Moy et al. (11)	*The postoperative results and handling aspects in patients after surgical treatment of skin cancers of Vicryl (PGLA) is less favourable, due to its tensile strength 2 weeks post implantation, compared to the tensile strength of Polytrimethylene carbonate.*
Thiede et al. (12)	*For Vicryl (PGLA) USP size 0 only a simple knot complexity is required. For the other sizes (USP 2 and 4) complex knots are necessary.*
Beauchamp et al. (7)	*The polyglycolic acid suture caused a slightly greater reaction sixteen days after suture placement in reproductive tract tissue than did Vicryl.*
Faulkner et al (13)	*Testing of the biomechanical performance of polyglactin 910 with different coatings showed a slight preference for a mixture of caprolactone and*

	glycolide (lactomer) as a coating material over a mixture of lactic acid 65% and glycolic acid 35% (Vicryl).
Debus et al. (14)	*comparison tests of Dexon, Dexon II bicolor, Vicryl and Polysorb (PGLA) were related to physical testing, in vivo testing and handling assessment. All sutures demonstrated also positive results, for Vicryl the slowest loss of function was observed.*
Rodeheaver et al. (15)	*Dexon and Dexon S polyglycolic acid sutures showed lower coefficient of friction, encountered less tissue drag forces, less flexural rigidity and less throws needed to achieve knot security compared to Vicryl (PGLA).*
Reul et al. (16)	*In contaminated or infected wounds, Vicryl sutures did not appear to convert contaminated wounds to an infected wound or to harbor and to prolong an infection, compared to silk or other multifilament non-absorbable sutures.*
Ratner et al. (17)	*Complete overview of available absorbable and non-absorbable sutures: Vicryl (PGLA) has good handling properties, its tendency to produce tissue reaction is mild to low, considered to be most useful as a buried intradermal suture, if placed too close to the surface of a cutaneous wound, Vicryl may be extruded, or spit, before dissolving completely*
Gabrielli et al. (18)	*In clinical investigations PGLA sutures show low tissue reactions and decreased incidence of infection and wound dehiscence*
Pandey S. et al. (19)	*Compared to non-absorbable Polypropylene (Prolene®) absorbable polyglactin 910 suture materials showed little higher rate of wound dehiscence after mass closure of vertical Laparotomy Wounds.*
Santos PS Filho et al. (20)	*A clinical trial comparing Polyglactin 910 suture with polyglactin 910 coated with triclosan used patients undergoing saphenectomy during CABG. In several test as presented infection and wound pain as well as Wound hyperthermia the coated version performed better than the uncoated.*
Tabrizi R et al. (21)	*A clinical trial comparing Polyglactin 910 suture with polyglactin 910 coated with triclosan in dental implant surgery didn't demonstrate any significant difference in the incidence of surgical site infection between the two groups.*
Pandey et al. (22)	*incidence of wound dehiscence with a delayed absorbable (Vicryl PGLA) was significantly higher compared to a non-absorbable (Prolene®) suture material in the mass closure of vertical laparotomy wounds.*
Amshel et al. (23)	*The use of Vicryl (PGLA) in gastrointestinal surgery was assessed as being favorable in general, especially in the presence of contamination or infection, since the rate of absorption is unaffected by the presence of inflammatory cells (in contradiction to surgical gut) and Vicryl retains adequate strength for 21-28 days.*
Robbs et al. (24)	*In colonic wounds in the rabbit – no significant differences in regard to wound strength of Polyglactin910 compared to other suture material 14 days after the surgery.*
Wasilijew et al (25)	*The experience of closure of abdominal incisions with regard to the risks of dehiscences and incisional hernia were considered to be favorable for Vicryl (PGLA)*
Kettle et al. (26)	*For wound closure during perineal repair, absorbable sutures (polyglycolic and polyglactin) showed favourable results in assessing short term pain, need for analgesia and suture dehiscence compared to catgut.*

Hosseini et al. (36)	*Vicryl sutures were associated with a lower risk of CSD formation in comparison with catgut sutures*
MBarki et al. (37)	*Comparison between polyglactin non coated suture VICRYL and polyglactin coated suture VICRYL Plus Triclosan coated suture are helpful in reducing surgical site infections rate and wound healing disturbances after caesarian delivery.*
Koroglu et al. (38)	*Comparison between polyglactin 910 or polypropylene for subcuticular skin closure after cesarean delivery. no difference was observed between the groups in terms of other wound complications*
DCunha et al. (40)	*Clinical equivalence of the two polyglactin 910 sutures Trusynth® and Vicryl® for subcutaneous tissue closure during cesarean delivery. Both Trusynth® and Vicryl® polyglactin 910 sutures are safe and effective for subcutaneous tissue closure during cesarean section with minimal risk of subcutaneous abdominal wound disruptions*
Tatar et al. (41)	*Comparison of traditional absorbable polyglactin 910 (Vicryl; Ethicon, Somerville, NJ, USA) and barbed sutures (V-Loc 180; Covidien, Mansfield, MA, USA) in laparoscopic myomectomy. No defined results*
Sharma et al. (42)	*Comparing subcuticular skin closure at cesarean delivery with poliglecaprone-25 vs polyglactin-910. Poliglecaprone-25 and polyglactin-910 subcuticular sutures were comparable regarding composite wound complications (surgical site infection, hematoma, seroma, wound separation or re-suturing, need for readmission) and cosmetic appearance (patient scar assessment score & observer scar assessment score) related to skin closure among women undergoing cesarean delivery*
Sobodu et al. (43)	*monofilament (poliglecaprone 25 or polypropylene) for subcuticular skin closure at CD was associated with decreased risk (not significant) of SSI compared to multifilament suture (polyglactin 910)*
Devi et al. (45)	*Comparison of the clinical equivalence of polyglycolic acid suture (Truglyde®) with polyglactin 910 suture (Vicryl®) for subcutaneous tissue closure following cesarean section. Non-significant differences were observed between the two treatment groups.*
As a result of the above-mentioned publications the biocompatibility characteristics of the PGLA material can be considered as mostly favourable for the use of this suture for tissue approximation respectively ligation.	

Application of PGLA in ophthalmology

***Table 2**: Summary of results of different clinical studies, trials and investigations regarding the use of PGLA in ophthalmology. If the studies refer to the use of a specific PGLA suture, the brand name is mentioned, even if these are not equivalent devices but only similar devices.*

Reference	***Content***
Neumann et al. (27)	*In the field of adjustable strabismus surgery 6 and 24 hours after the initial procedure sutures made from polyglycolic acid were found to be favourable over Polyglactin 910 (Vicryl, PGLA), for Vicryl the adjustment of the muscle was considered to be easier at 6 hours rather than after 24 hours*
Apt et al. (28)	*Dexon and Vicryl (PGLA) used in strabismus surgery showed advantages in comparison to catgut and collagen such as superior tensile strength, rapid absorption in a predictable manner, reduced tissue reaction with no antigenicity since they are non-protein and excellent handling and knot-tying qualities. Disadvantage is the reduction of the easy passage of the*

	suture through tissue that makes tying of knots difficult and prevents secure knot-typing.
Stein et al. (29)	*In a retrospective case series surgical revisions of the very rare case of performed owing to hypotony from overfiltration in the absence of a wound leak were identified. 50% treated by using polyglactin suture ligation were successful and did not require additional surgery – compared to 80% undergoing suture ligation using prolene*
Bainbridge et al. (30)	*10/0 monofilament absorbable polyglactin suture was used for temporal 5.2 mm corneal incision phacoemulsification. The sutures maintain adequate tensile strength and was associated with a minimal induction of astigmatism and a mild degree of local tissue reaction*
Salamah et al. (39)	*Comparison of the efficacy of two different suture types in levator plication for correction of congenital ptosis. No differences between double-armed 5/0 polyester Ethibond and doublearmed 5/0 Coated Vicryl® (polyglactin 910) suture*
Savran et al. (44)	*Comparison of the cosmetic outcomes of the use of absorbable polyglactin 910 (PG) (Vicryl Rapide 5/0; Ethicon Inc.) and nonabsorbable polypropylene (PP) (Prolene 5/0; Ethicon Inc.) in open septorhinoplasty to enhance nasal function and appearance in terms of surgical scarring. There was no significant difference between the groups in any of the parameters investigated within the scope of the study.*
Summarizing the results of the above-mentioned publications the biocompatibility and other characteristics of the PGLA material can be considered as mostly favorable for the use of this suture for ophthalmology.	

6.3.2 Current appraisal of literature for absorbable sutures

In the scientific literature found, it is concerned only with straight applications of the Assut sutures within the respective study; the safety and performance of the Assut sutures was always considered in the overall context of the respective indication or surgical method. None of the scientific studies found showed any negative abnormalities with regard to the safety and performance of the Assut sutures. By implication, this means that the use of Assut sutures has proven to be safe and effective.
The goal in the study of Atef et al (2020) (35) was to evaluate the quantity and the quality of the bone gained using collagen membrane with 1:1 mixture of autogenous and anoraganic bovine bone mineral compared to titanium mesh with the same mixture of bone for GBR of horizontally deficient maxillary ridges. Two different grafting techniques were evaluated, 10 patients receiving GBR using native collagen membrane using 1:1 autogenous and anorganic bovine bone mineral (ABBM) bone mixture, and 10 patients receiving GBR using titanium mesh with same mixture of bone. During the procedure, the donor site at the chin was closed in two layers, the deep muscular layer was first sutured using 4-0 resorbable interrupted sutures (Polyglactin, Assut, Switzerland) and the mucosal layer was then closed using simple interrupted sutures with 5-0 synthetic monofilament suture (Prolene, Assut, Switzerland).

In the literature searches carried out until December 31, 2024, no relevant literature with Assut AssuCryl® Lactin was found following our surveillance criteria whether there are any new or updated data on the clinical safety and performance of the Assut Sutures.

6.3.3 Complications and Side-Effects (similar products)

One case of unexpected tissue reactions (inflammation, granuloma, extrusion, fistula, abscess) after clean surgery has been reported (Holzheimer et al., (31)). These tissue reactions have been observed in patients with subcuticular sutures as well as in patients with deeper located vein ligatures. The observed almost all 12 cases of these effect within several weeks in summer 2005, which is why the reason for the tissue reaction might not be caused by the suture but by another unsolved cause.

6.3.4 Clinical benefit

Summarising all clinical data described above, using AssuCryl® Lactin has the following clinical benefits which are also addressed in the IFU:

- AssuCryl® Lactin can be absorbed by the body without removing the thread.
- A follow-up visit to remove the patient's sutures is not required and consequently reduces the possibility of scarring and infection.
- No foreign body left after complete absorption
- Save time
- Easy to handle
- High tensile strength
- Excellent knotting security
- Very low capillarity

6.4 Summary of clinical performance and safety

The evaluation of the clinical data for the AssuCryl® Lactin absorbable surgical sutures made from polyglactin (PGLA) showed that there is sufficient clinical data that confirm the safety and the performance of the devices. The AssuCryl® Lactin sutures can be considered as similar to other PGLA on the market as they have the same intended use, the same mode of action and a comparable design concept.

Therefore, it can be stated that the clinical experience with absorbable surgical sutures is huge since the 1980ies and the application of the absorbable surgical sutures is part of the general surgical procedures.

Severe complications with absorbable surgical sutures are uncommon.

The AssuCryl® Lactin sutures - as its predicate devices - consist of materials suitable for medical long-term implants and proved to be biocompatible. The biological safety of the devices has been carefully investigated and proved.

The AssuCryl® Lactin sutures comply with the state-of-the-art technical standards which is the European Pharmacopoeia Monograph 01/2008:0667 and the accordant USP standard. The products can be considered as comparable with the similar devices identified (Dexon, PGA Resorba, Safil, Safil quick). No further risks are generated.

The safety of the AssuCryl® Lactin sutures is confirmed by the vigilance data gained through research at the competent authorities of Germany (BfArM), Switzerland (Swissmedic) and USA (FDA). No unknown risks or side effects have been identified.
As a result of the above-mentioned publications and evaluation the biocompatibility, physical and chemical characteristics of the PGLA material are considered as favorable for the use of this suture for tissue approximation respectively ligation, which corresponds perfectly to the claimed intended use. The results obtained in the clinical evaluation confirm that the benefit outweighs the risks associated with the use of the AssuCryl® Lactin sutures and that the medical devices comply with the General Safety and Performance Requirements of Medical Device Regulation (EU) 2017/745.

Based on the clinical literature data reviewed it is concluded that risk-benefit ratio for the AssuCryl® Lactin sutures is positive for the intended use.

6.5 Post-market clinical follow-up

The PMCF is a part of the clinical evaluation, which includes post market studies to demon-strate the safety and performance of the medical device. PMCF runs parallel with the pro-cesses of controlling literature review and vigilance reporting, field safety corrective actions (FSCA), complaints and other feedback from the market.

PMCF is a continuous process that updates the clinical evaluation which is planned as part of the post-market surveillance (PMS) plan.

In its essence, PMCF is a systematic collection of clinical data, documentation and evidence with the purpose of proactively uncovering important safety or performance issues in AssuCryl® Lactin and updating its clinical evaluation. PMCF supplements the existing pre-market clinical and non-clinical data. PMCF activities runs on a continuous basis throughout the entire lifetime of a medical device. Its specific objectives include:

- Identifying and investigating residual risks associated with use of the device
- Contributing towards the update of Clinical Evaluation
- Detecting any emerging risks and previously unknown side-effects
- Confirming the overall safety and performance of the medical device in normal use
- Identifying systematic misuse of the device and its impact on safety and performance

If any emerging risks, complications or unexpected device failures have been detected and reported by user to Assut, Assut treats them as complaints and manages them within CAPA processes and evaluates them as part of the PMS activities. In case of new, previously unknown risks, they will be included and considered in the risk management.

6.6 Adverse events

An adverse event means any untoward (unfortunate) medical occurrence, unintended disease or injury or any untoward clinical signs, in subjects, users or other persons.
During the last five years (2020 to 2024), we had 1 adverse event reported for our AssuCryl® Lactin (PGLA). A mix of diameters, but without any clinical adverse event.
See table below with the rate (%) for AssuCryl® Lactin (extract from PSUR report):

		Numbers of justified complaints											
Type of sutures	Basic UDI-DI	2024.	2023.	2022.	2021.	2020.	Total.	Qty concerned in doz 5 year	Qty concerned in % for 5 year	Type of complaint	Vigilance / FSCA /Recall	Severity of complaint *	Remarks
AssuCryl Lactin (PGLA) violet	07613406ACLLPGLAHT				1		1	61	0.036%	Diameter	YES	NS	USP size not correct, but no risk for the patient
AssuCryl Lactin (PGLA) undyed	07613406ACLLPGLAHT						0						

Every feedback from the market (complaints, vigilances, etc.) is an input for risk management process and permits adjustment of risk probability rate according to Risk Management Plan.

That risk probability rate is multiplied with a risk severity rate (depending of the risk itself) to define the risk criticity level. A risk is acceptable only if the risk criticity level is LOW according to Risk Management Plan.

Note that a moderate risk can be acceptable if it can be proven that the benefit-risk ratio is positive.
Conclusion: For AssuCryl® Lactin, there was 1 complaint and vigilance case between 2020 to 2024, rate = 0.036%; all risks associated to AssuCryl® Lactin are low and acceptable.
The device is safe and the benefit-risk ratio is **POSITIVE**.

7 Possible diagnostic or therapeutic alternative

With regard to skin closure, the skin incision can be re-approximated by a subcuticular suture immediately below the skin layer, by an interrupted suture, or by staples.

Professional guidelines recommend the application of surgical sutures for different surgical procedures. Example is the guideline No. 23 "Methods and materials used in perineal repair" published by the Royal College of Obstetricians and Gynaecologists (32).

Technical specifications for absorbable surgical sutures are described in the monographs of USP and European Pharmacopeia (33). Both monographs define the suture sizes, breaking loads and strength of needle attachment. PGLA sutures comply with the requirements of the Ph. Eur. Monographs and the United States Pharmacopeia (USP).

Based on a yearly literature searches and analysis which is detailed in the Clinical Evaluation Report, the sutures AssuCryl® Lactin, under evaluation as conventional sterile synthetic absorbable sutures, remains to be the state-of-the-art wound closure techniques. During the last years using a triclosan coating to reduce surgical site infections (Depuydt et al. (46), Erfan et al. (47), Sandhya et al. (48) becomes more relevant but there are still no all-encompassing therapeutic alternatives replacing surgical sutures in general.

8 Suggested profile and training for users

The Assucryl® Lactin, part of product family of “absorbable surgical suture” are intended to be used by trained medical staff healthcare professionals that have already experience using such sutures exclusively.

9 Reference to any harmonised standards and CS applied

The document “Search for Applicable Standards absorbable” is reviewed every year and available upon request.

The list below is valid from May 2025:

Standards ID	Description	Revision / Year
EN 556-1:2024	Sterilization of medical devices – Requirements for medical devices to be designated “STERILE” – Part 1: Requirements for terminally sterilized medical devices	2024
EN 868-5:2018	Packaging for terminally sterilized medical devices - Part 5: Sealable pouches and reels of porous materials and plastic film construction - Requirements and test methods	2018
EN ISO 10993-9:2021	Biological evaluation of medical devices - Part 9: Framework for identification and quantification of potential degradation products (ISO 10993-9:2009)	2021
EN ISO 10993-10:2023	Biological evaluation of medical devices - Part 10: Tests for skin sensitization (ISO 10993-10:2021)	2023
EN ISO 10993-12:2021	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (ISO 10993-12:2021)	2021
EN ISO 10993-15:2023	Biological evaluation of medical devices - Part 15: Identification and quantification of degradation products from metals and alloys (ISO 10993-15:2019)	2023

EN ISO 10993-17:2023	Biological evaluation of medical devices - Part 17: Toxicological risk assessment of medical device constituents (ISO 10993-17:2023)	2023
EN ISO 10993-18:2020/A1:2023	Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process (ISO 10993-18:2020+ Amd 1:2022)	2023
EN ISO 10993-23:2021	Biological evaluation of medical devices - Part 23: Tests for irritation (ISO 10993-23:2021)	2021
EN ISO 11137-1:2015/A2:2019	Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 11137-1:2006, including Amd 1:2013)	2019
EN ISO 11137-2:2015 /A1:2023	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose (ISO 11137-2:2013 + Amd 1:2022)	2023
EN ISO 11607-1:2020 + A1:2023	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2019 + Amd 1:2023)	2023
EN ISO 11607-2:2020 + A1:2023	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2019 + Amd 1:2023	2023
EN ISO 11737-1:2018 + A1:2021	Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2018)	2021
EN ISO 11737-2:2020	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (ISO 11737-2:2019)	2020
EN ISO 13485:2016 + AC:2018 + A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)	2021
EN ISO 14971:2019 + A11:2021	Medical devices - Application of risk management to medical devices	2021
EN ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1:2021)	2021
EN ISO 11135:2014 + A1:2019	Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices	2019
Eur. Pharmacopeia Edition 11 (version 11.8)	Sterile synthetic absorbable sutures braided and monofilament	2025

10 Revision history

See above (top of document).

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