Assut sutures of Switzerland

Summary of Safety and Clinical Performance (SSCP)

Absorbable Surgical suture

AssuCryl® Rapid

CE-Mark since 2012

VERSION 06

24.07.2025

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
PGA /PGAR	Polyglcolic Acid / Polyglcolic Acid Rapid
O.R.	Operating Room
Tricarboxylic	Organic compound containing three carboxyl (functional group of general formula) groups

Revision history

Revision 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	07.06.2022	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	24.07.2025	EMDN codes revised for level 6	☐ **YES** **Validation language: English** ☐ **NO** (Only applicable for class IIa and some IIb implantable devices for which the SSCP is not yet validated)

Approval:

	Author	**Reviewed by**	**Released by**
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Name:	Barbara Kathage	Catherine Baerfuss	Marc Baerfuss
Date:	24.07.2025	24.07.2025	24.07.2025
Signature:			

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1. Introduction

This summary of safety and clinical performance (SSCP)for the surgical absorbable suture AssuCryl® Rapid manufactured by Assut Medical Sarl 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.

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 exclude the italics part of the chapters 6.1, 6.1.1, 6.3 and 6.3.1, 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® Rapid
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	07613406ACLRPGACE
Class of the device	Class 3, Rule 8, Annex VIII, MDR
Year when the device was CE-marked	2012
Authorised representative (name, address, SRN)	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:** H0101010201 POLYGLYCOLIC ACID MULTIFILAMENT

3. Intended use of the device

3.1 Intended purpose/intended use and indications/application

AssuCryl® Rapid braided sutures are intended for use in general soft tissue approximation and/or ligation where only short-term wound support is required and when rapid absorption is indicated. It is also an indicated for superficial skin closure, plastic surgery, episiotomy wound healing, oral mucosa and conjunctival ophthalmic surgery.
AssuCryl® Rapid 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

Because of its rapid tensile strength loss AssuCryl® Rapid should not be used where extended approximation of tissues under tension is required beyond 6 days. AssuCryl® Rapid is not intended for use in cardiovascular and neurosurgery.

4. Device Description

4.1 Device description

AssuCryl® Rapid is a braided synthetic absorbable suture made of ≥ 95% of polyglycolic acid and ≤ 5% of Polycaprolactone and calcium stearate.
AssuCryl® Rapid 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® Rapid 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® Rapid meets all requirements established by the United States Pharmacopeia (USP) for absorbable surgical sutures and the European Pharmacopeia (Eur. Ph.) for synthetic braided absorbable sterile sutures, current editions.

Once AssuCryl® Rapid 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® Rapid will occur by means of hydrolysis. Implantation studies indicate that AssuCryl® Rapid braided suture material maintains approximately 50% of its original tensile strength after 6-9 days and practically none after 17-21 days. Absorption begins with a loss of tensile strength followed by a loss of mass and is essentially complete by 40-45 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® Rapid.

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.
The degradation product, glycolic acid, is nontoxic and it can enter the tricarboxylic acid cycle after which it is excreted as water and carbon dioxide. A part of the glycolic acid is also excreted by urine. 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® Rapid 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 orthopaedic

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® Rapid - 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. Make sure that used needles are disposed of properly by means of suitable containers and according to national rules.

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.
During the reviewed time interval there have been no incidents and no FSCA for the product category. 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. 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 (PGA)

Aliphatic polyesters such as polyglycolic acid (PGA) are biodegradable polymers because of the presence of the highly hydrophilic carbonyl in the ester linkage which undergoes hydrolytic and/or enzymatic chain cleavage to hydroxy acids, which in most cases are ultimately metabolized in human body.

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. PGA undergoes hydrolytic degradation through the nonspecific scission of the ester backbone. The degradation process is erosive and appears to take place in several steps during which the polymer is converted back to its monomer glycolic acid: the first step involves diffusion of water into the amorphous (non-crystalline) regions of the polymer matrix, cleaving the ester bonds; the second step starts after the amorphous regions have been eroded, leaving the crystalline portion of the polymer susceptible to hydrolytic attack. Upon collapse of the crystalline regions, the polymer chain dissolves.

When exposed to physiological conditions, PGA is also broken down by certain enzymes, especially those with esterase activity.

***The degradation product, glycolic acid, is nontoxic** and it can enter the tricarboxylic acid cycle after which it is excreted as water and carbon dioxide. A part of the glycolic acid is also excreted by urine. Studies carried out using sutures made from PGA have shown that the material loses half of its strength after 2 weeks and 100% after 4 weeks. The polymer is completely resorbed by the organism in a timeframe of 4–6 months.*

The absorption of water and its penetration into the interior of PGA, PLA, and their copolymers initiate hydrolytic fragmentation degradation followed by the reduction of mechanical properties. The degradation of PGA is faster than that of PLA. Unlike PLA, extracellular enzymes are also thought to have a role in in vivo degradation of PGA.

The glycolate generated from PGA during final hydrolysis is either excreted directly in the urine or is oxidized to glyoxylate that gets converted to glycine, serine, and pyruvate (4).

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 (6). This explains the difference in findings for the degradation in clinical investigations.

The rate of degradation in biological tissue is defined by the "half-life tensile strength". It gives the time at which still 50% of the original tensile strength is found. Half-life tensile strength of PGA has been demonstrated to be about 2 weeks, whereas monofilament absorbable sutures have longer half-life tensile strength (7). Other authors report a loss in tensile strength of about 40% after 7 days. By 15 days it had lost more than 80% of its original strength, and is completely dissolved by 90 to 120 days (8).

The fast absorbing PGARs have a higher absorption time as the PGA threads ranging from approximately 17-21 days after implantation.

6.2 Clinical evidence for the CE-marking

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

6.3 Summary of clinical data from other sources

Since its invention in 1970 (9), polyglycolic acid (PGA) based synthetic absorbable sutures are widely used around the world where temporary support for tissue approximation is required. Since its invention, PGA based absorbable surgical sutures have been the most preferred suture type among absorbable sutures. AssuCryl® Rapid is made from a synthetic absorbable braided coated suture material composed of Polyglycolic acid (PGA) like AssuCryl®. The very fast absorption time is achieved by a special manufacturing process based on artificial degradation method (temperature exposition) with a crystallinity control, but the raw material PGA remains the same as for AssuCryl®. Due to the fact that fast absorbable sutures are relatively new on the market compared to other absorbable sutures we base our assessment of literature for the clinical evaluation and the benefit-risk-ratio on clinical data to the raw material PGA in general.

Polyglycolide or Poly (Glycolic Acid) (PGA) Poly(-esters) are thermoplastic polymers with hydrolytically labile aliphatic ester linkages in their backbone. PGA is the simplest linear aliphatic polyester.

Product made from PGA has been used widely as a biocompatible and biodegradable material for tissue engineering (10,11). Consequently, the material has been used for a variety of medical applications like material for bone implants (12), bone fixation devices (13,14), anastomotic devices (15), stents (16), scaffold to support osteoblastic cells and bone growth (17), and absorbable sealing

material (18). retrospective study to evaluate the efficacy and safety of an absorbable polyglycolic acid (PGA) patch in surgery for refractory pneumothorax due to silicosis.

Summarizing literature articles describe the excellent performance (19,20), combined with biocompatibility (21) and product safety (22) of the PGA based surgical sutures. The advantage of the material is that neither the polymer nor its degradation product glycolic acid are toxic when implanted in vivo (9).

In clinical investigations PGA sutures show less tissue reactions (23) and decreased incidence compared to other surgical sutures of the group synthetic absorbable sutures. Therefore PGA synthetic absorbable suture material is the first choice in the majority of the surgical procedures. e.g. surgery of gastrointestinal tract and respiratory organs (24), subcutaneous and intra oral sutures (25), obstetric surgery (26).

PGA is particularly useful in subcutaneous and intracutaneous closures, abdominal, and thoracic surgeries. With its high initial tensile strength, it has guaranteed holding power through the critical wound healing period. This suture being absorbable should not be used where extended approximation of tissue is required. Special precautions should be taken in elderly patients and patients with history of anemia and malnutrition conditions. As with any suture material, adequate knot security requires the accepted surgical technique of flat and square ties (4).

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 (2).

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 [2])*

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

Reference	***Content***
Balamurugan et al. (27)	*PGA material is far superior than black silk on various criteria's like retention strength, tissue reaction, knotting capacity and handling characteristics in fibrous gingiva and oral mucosa.*
Dardik et al. (4)	*PGA exhibited excellent behavior so that it could be termed a ‘‘universal’’ suture material. PGA appears to compare favorably with other sutures with respect to handling, tensile strength, knot security, lack of toxicity, and minimal tissue reaction.*
Debus et al. (28)	*PGA suture material demonstrates positive results in physical testing, in vivo testing and handling assessment. Polysorb reached the best results among different sutures.*
Rodeheaver et al. (25)	*The results were in favor of the polyglycolic acid for the items tested: lower coefficient of friction, encountered less tissue drag forces, less flexural rigidity*
Neumann et al. (29)	*The results obtained after adjustable strabismus surgery with the three different sutures supported the use of PGA suture material for 6 and 24 hours after the initial procedure.*
Apt et al. (30)	*Dexon and Vicryl 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. The biocompatibility and other characteristics of the PGA material can be considered as favourable for the use of this suture for ophthalmology*
Nk et al. (56)	*Truglyde Fast® and Safil Quick® were compared regarding their Clinical Equivalence for Episiotomy Repair Following Vaginal Delivery. Truglyde Fast® polyglycolic acid fast-absorbing suture beeing clinically equivalent to the Safil Quick® polyglycolic acid fast-absorbing suture as non-significant differences regarding both primary and secondary endpoints (except the number of sutures used and intraoperative suture handling) were recorded*
Devi et al. (57)	*Comparison of sutures made from PGA with sutured made from polyglactin 910 with regard to subcutaneous tissue closure after cesarean delivery. Non-significant differences were observed between the two treatment groups. Following cesarean section, subcutaneous tissue closure using polyglycolic acid suture or polyglactin 910 suture was not associated with incidence of subcutaneous abdominal wound disruptions. Additionally, non-significant differences regarding secondary endpoints between the groups suggested the clinical equivalence of the sutures.*
As a result of the above-mentioned publications the biocompatibility characteristics of the PGA material can be considered as favourable material or at least equal to other materials for tissue approximation respectively ligation. **The new literature searches performed annually in line with the PMS and PMCF activities did not identify any unknown risks or aspects referring to clinical performance or safety or both.**	

6.3.1 Rapid absorbing material

Rapidly resorbing suture material has been published in literature only recently as this type of material is on the market since few years now. The difference of the two products lies in the higher absorption time which is achieved by a structure modification of the molecules of the thread so that a fast absorbing material is obtained.

***Table 2**: Summary of results of different clinical studies, trials and investigations regarding the use of PGA Rapid in general soft tissue approximation and/or ligation*

Reference	***Content***
Cremers et al. (31)	*The tested materials Vicryl-Rapide and Safil Quick were similar with regard to most aspects of their clinical suitability as discomfort or pain for the patient, good knot security and tensile strength, predictable resorption, minimal tissue response, and good wound healing.*
Ivanoff et al. (32)	*Rapidly resorbing suture material (Vicryl-Rapide) was found to be a cost effective choice for closing the skin of invaginal hernia repairs and probably of other clean operations.*
Brackeen et al. (33)	*A clinical study concluded that irradiated polyglactin 910 (Vicryl-Rapide) provides another option for the placement of full-thickness skin grafts without the need for suture removal*

6.3.2 Current appraisal of literature for absorbable sutures dated 12.12.2022

In the literature review carried out in December 2022, it was assessed within the context of the Post Market Surveillance criteria whether there are any new or updated data on the clinical safety and performance of the Assut Sutures.
The following applications or indications, which are also described in the Instructions for Use, were found with regard to Assut sutures:

- General soft tissue approximation and/or ligation [1]
- Ophtalmic Surgery [2]

Reference	***Content***
Beer-Seeva et al. (35)	*[1] Fat pads were rinsed with 0.9% saline and stitched to the mesenterium of the recipient mouse using Assucryl 6.0 (Assut-Medical, Corgemont, Switzerland). Sham-operated control mice underwent the same procedure, but, instead of fat pad transplantation, an artificial suture was performed with AssuCryl®. The peritoneum was sealed by AssuCryl® 5.0.*
Linkevicius et al. (36)	*[1] Eighty patients (38 male and 42 female, mean age 44 ± 3.34 years) received 80 bone-level implants that were placed with a one-stage approach and restored with screw-retained restorations. The flaps were closed without tension with 5/0 interrupted sutures (AssuCryl®, Assut Medical Sarl, Lausanne, Switzerland).*
Ramot et al. (37)	*[1] To evaluate in a GLP-compliant study in domestic pigs the local reaction and performance of a novel fractional RF device biopsied were harvested. Open wounds were sutured with appropriate suturing material (AssuCryl® 2-0, Assut Sutures, Lausanne, Switzerland), polydine solution was applied, and a stockinet was applied on the animal's body.*
Mahmoud et al. (38)	*[1] To evaluate implant primary stability using Densah bur in comparison with expanders in maxillary premolar area this study was conducted on twenty patients. During implant placement a healing collar was placed on the implant, then the flap was approximated and sutured (AssuCryl® PGA Synthetic absorbable) around healing collar.*
Shawky et al. (39)	*[1] A 15 years old male patient with mandibular asymmetry and class IV recurrent ankylosis of the right TMJ received a patient-specific artificial joint. The intraoral wound was closed after insertion of the prosthesis with a running 3-0*

	vicryl (AssuCryl®, Assut, Switzerland), both the retromandibular and endaural approaches were closed in layers, and the skin was closed with polypropylene 4-0 (Assut, Switzerland).
Veljanovski et al. (40),	*[1] In the case study two implants were places at sites 23 and 26 to support a fixed partial denture (FPD). The bone replacement material was covered with a resorbable membrane that was positioned and stabilized with a horizontal mattress suture using an absorbable 5.0 PGA suture (Assut Medical, Lausanne, Switzerland). Later in the process the soft tissues were closed utilizing double sling 5.0 polypropylene sutures (Assut Medical, Lausanne, Switzerland) to ensure a passive closure of the wound. The graft was placed and sutured to the surrounding tissue using 6.0 polyproplylene sutures (Assut Medical, Lausanne, Switzerland), which were finally removed two weeks later.*
El Rayes et al. (41)	*[1] To demonstrate demonstrating soft tissue dehiscence ten patients receive received a de-epithelialized connective tissue graft harvest from the anterio-lateral hard palate combined with a coronally advanced flap. The flap was then closed using 4.0 resorbable polyglycolic acid suture material (AssuCryl®, Assut, Switzerland) in an interrupted or continues fashion. The flap was released with periosteal incisions using a 15 blade for tension free closure, an apical periosteal horizontal mattress suture was used to detour tension from the incision line and ensure tension free closure using a 4.0 polypropylene suture (Assut, Switzerland) the flap corners were then closed followed by the horizontal incision and the vertical incision, using multiple interrupted 4.0 polypropylene sutures.*
El Aziz et al., (42)	*[1] To evaluate the aesthetic outcome and stability of gingival tissue and crestal bone level over immediate implants using connective tissue graft, 16 patients are receiving an implant under different conditions. Horizontal mattress suture was used to ensure graft stability in the recipient site using resorbable suture (Vicryl 5.0, Assut suture 5-0, Switzerland). Flaps were closed with interrupted sutures at both sites and figure eight using non-resorbable suture (Blueproline 5.0 suture, Assut suture 5-0, Switzerland) in both groups.*
Ghoraba et al (43)	*[2] The safety and efficacy of different methods of transconjunctival cannulated vitrectomy versus conventional non-cannulated vitrectomy in various vitreoretinal disorders was evaluated. If any of the ports demonstrated persistent leakage, the sclerotomy site was closed, either transconjunctivally or transsclerally using 7-0 Vicryl (PGA) sutures, AssuCryl®, Pully-Lausanne, Switzerland.*
Omar et al. (44)	*[2] To evaluate the corneal topographic changes following pterygium surgery using sutured conjunctival autografting versus sutured amniotic membrane grafting this study was performed. Either type of graft was then sutured using 8/0 vicryl suture (AssuCryl®, Assut Medical, Switzerland) and the eye was patched.*
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.	

In the literature searches carried out until December 31, 2024, one relevant publication with Assut AssuCryl® Rapid was found following our surveillance criteria about are any new or updated data on the clinical safety and performance of the Assut Sutures.

In the case study by Veljanovski et al. in 2021 (58), two implants were places at sites 23 and 26 to support a fixed partial denture (FPD). The mesial implant showed exposed buccal threads, which were then covered with autogenous bone particles and small size granules of deproteinized bovine bone material. The bone replacement material was covered with a single layer of a resorbable membrane (Bio-Gide®, Geistlich, Wolhusen, Switzerland). This membrane was positioned before the application of the bone graft materials and it was stabilized with a horizontal mattress suture using an absorbable

5.0 PGA suture (Assut Medical, Lausanne, Switzerland). The sutures were passed through the periosteum at the apical part of the flap and tied to the palatal mucosa. A superficial submucosal incision (periosteum splitting) was done in order to enable flap mobility for primary closure. The soft tissues were closed utilizing double sling 5.0 polypropylene sutures (Assut Medical, Lausanne, Switzerland) to ensure a passive closure of the wound. The graft was placed and sutured to the surrounding tissue using 6.0 polyproplylene sutures (Assut Medical, Lausanne, Switzerland), which were finally removed two weeks later.
Absorbable 5.0 PGA suture (Assut Medical, Lausanne, Switzerland) as well as 5.0 and 6.0 polypropylene sutures (Assut Medical, Lausanne, Switzerland) were used to close soft tissue wounds after implantation without any unknown or severe complications/risks.

6.3.3 Complications and Side-Effects

The complications and side-effects associated with polylactic acid absorbable surgical sutures are well known and are discussed in the above chapter for each of the identified clinical trials.
One case of unexpected tissue reactions (inflammation, granuloma, extrusion, fistula, abscess) after clean surgery has been reported (Holzheimer et al., (34)). 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 benefits

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

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

6.4 Summary of clinical performance and safety

The evaluation of the clinical data for the AssuCryl® Rapid absorbable surgical sutures made from polyglycolic acid (PGA) showed that there is sufficient clinical data that confirm the safety and the performance of the devices. The AssuCryl® Rapid sutures can be considered as similar to other PGA Rapid in 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® Rapid 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.

Absorbable surgical sutures made from polyglycolic acid (PGA) are widely used since 1970ies in different types of surgery, including orthopedic surgery. The AssuCryl® Rapid 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 predicate devices identified (Dexon, PGA Resorba, Safil, Safil quick). No further risks are generated.

The use of absorbable surgical sutures can be considered as the state-of-the-art technology for surgical wound closure including orthopaedic surgeries. The efficacy and safety of the products has been well-established.

The safety of the AssuCryl® Rapid sutures is confirmed by the vigilance data gained through a 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 PGA 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® Rapid sutures and that the medical devices comply with the General Safety and Performance Requirements of Medical Device Regulation (EU) 2017/745, including GSPR1, GSPR2, GSPR4, GSPR5 on performance and safety of the device.

Based on the clinical literature data reviewed in this clinical evaluation it is concluded that risk-benefit ratio for the AssuCryl® Rapid 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 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® Rapid 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 no adverse event reported for our AssuCryl® Rapid (PGA).
See table below with the rate (%) for AssuCryl® Rapid (extract from PSUR report):

		Sales in dozen						Numbers of justified complaints										
Type of sutures	Basic UDI-DI	2024	2023	2022	2021	2020	Total	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 Rapid (PGA) undyed	07613406ACLRPGACE	11 094	10 598	12 600	9 436	10 149	53 877						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® Rapid, there was no complaint and no vigilance case between 2020 and 2024, rate = 0%; all risks associated to AssuCryl® Rapid 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 (4).

Technical specifications for absorbable surgical sutures are described in the monographs of USP and European Pharmacopoiea (5). Both monographs define the suture sizes, breaking loads and strength of needle attachment. PGA sutures comply with the requirements of the Pharm. Europ. 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® Rapid, under evaluation as conventional sterile synthetic absorbable sutures, remains to be the state-of-the-art wound closure techniques.

8. Suggested profile and training for users

The AssuCryl® product family “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

10. Revision history

See above (top of document).

11. Literature

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