Assut sutures of Switzerland

Summary of Safety and Clinical Performance (SSCP)

Absorbable Surgical suture

AssuCryl® MonoRapid

CE-Mark since 2013

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
PGCL	Polyglecaprone
PGCL	Polyglecaprone
O.R.	Operating Room

Revision history

Version number	Date issued	Change description	Validated by Notified Body
00	26.08.2021	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	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:

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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® MonoRapid 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.

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 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® MonoRapid
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	07613406ACLMRPGCL25
Class of the device	Class 3, Rule 8, Annex VIII, MDR
Year when the device was CE-marked	2013
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 :** H0101010103 POLIGLECAPRONE AND DERIVATIVES MONOFILAMENT

3. Intended use of the device

3.1 Intended purpose

AssuCryl® MonoRapid monofilament sutures are intended for use in general soft tissue approximation and/or ligation when only short-term wound is required and rapid absorption is indicated. It is also ideal for sutures of the epidermis, plastic surgery, healing an episiotomy and suture of the mucous membranes.
AssuCryl® MonoRapid 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

Due to its rapid loss of tensile strength, AssuCryl® MonoRapid must not be used when extensive closure of the tissue is required for an extended period of time. AssuCryl® MonoRapid is not intended for use in cardiovascular, neurological tissues, microsurgery and ophthalmic surgery.

4. Device Description

4.1 Device description

AssuCryl® MonoRapid is a monofilament synthetic absorbable suture prepared from a copolymer made of ≥ 99.9 of poly(glycolide-co-epsilon-caprolactone) and ≤ 0.1% of dye for the violet colour.
AssuCryl® MonoRapid 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® MonoRapid 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.

AssuCryl® MonoRapid meets all requirements established by the United States Pharmacopeia (USP) for absorbable surgical sutures and the European Pharmacopeia (Ph. Eur.) for synthetic monofilament absorbable sterile sutures, current editions.

Once AssuCryl® MonoRapid has been implanted there may be a faint reaction to a foreign body with a moderate initial inflammatory reaction. Progressive loss of tensile strength and absorption of AssuCryl® MonoRapid will occur by means of hydrolysis. Implantation studies indicate that the AssuCryl® MonoRapid monofilament suture retains approximatively 50% of its initial tensile strength after 6 to 8 days and practically none after at 21 days. Absorption begins as a loss of tensile strength followed by loss of mass and is essentially complete between 90 to 120 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® MonoRapid.

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 of glycolide copolymers - here polyglecaprone 25 - generally involves random hydrolysis of their ester bonds. The degradation is mainly based on hydrolysis and the degradation products can be 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® MonoRapid 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. Special care should be taken in regard to adequate knot security when using synthetic monofilament sutures.

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® MonoRapid - 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 related 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 (2).

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 (1).

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.

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. The polyglecaprone 25 surgical sutures are not coated.

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 (1).

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 (PGCL)

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.

The degradation of glycolide copolymers- here polyglecaprone 25 - generally involves random hydrolysis of their ester bonds. The degradation is mainly based on hydrolysis (3). The rate of degradation in biological tissue is defined by the "half-life tensile strength". It determines the time at which still 50% of the original tensile strength is found.

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 (4).

Polyglecaprone 25 is a material that is used by surgeons for procedures that require high initial tensile strength diminishing over 2 weeks postoperatively. These include subcuticular closure and soft tissue approximations and ligations, with the exception of neural, cardiovascular, ophthalmic, and microsurgical applications. All of the original tensile strength of undyed Monocryl Suture is lost by 21 days post implantation. Absorption is essentially complete at 91 to 119 days (Ethicon).

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.

Polycaprolactone is widely used in biodegradable implants such as a Capronor™ contraceptive system. Based on a large number of tests ε-caprolactone and polycaprolactone are currently regarded as non-toxic and tissue-compatible materials (5).

Summarizing literature articles describe the excellent biocompatibility and product safety of the Polyglecaprone 25 based surgical sutures.

6.2 Clinical evidence for the CE-marking

No clinical investigations have been conducted before the CE-marking of Assucryl® MonoRapid.

6.3 Summary of clinical data from other sources

Polyglecaprone (PGCL) based sutures are monofilament sutures and introduced as Monocryl in 1994 (6). Since its invention PGCL 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® MonoRapid is a legacy device which is on the market since since 2013, 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 PGCL in general soft tissue approximation and/or ligation

Monocryl Sutures are used for procedures that require high initial tensile strength diminishing over 2 weeks postoperatively. These include subcuticular closure and soft tissue approximations and ligations, with the exception of neural, cardiovascular, ophthalmic, and microsurgical applications (7).

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 (8).

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 [8])*

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

Reference	***Content***
9, 10, Ishikawa et al. (11)	*Monocryl (PGCL) has good handling and knotting qualities as well as a good tensile strength and minimal resistance during passage through tissue, it provides an **in vivo** breaking strength retention of approximately 20–30% after 2 weeks, considered by many to be the critical wound healing period*
Ishikawa et al. (11)	*low incidence of severe adhesions observed for the absorbable monofilament Poliglecaprone 25 suture in the peritoneal cavity in rats was observed.*
Regan et al. (13)	*Poliglecaprone-25 resulted in significantly fewer extruded sutures than did polyglactin-910, although both caused the same degree of lumpiness and resulted in similar-appearing scars at 1 week and 3 months*
Breuninger et al. (10)	*no significant difference in scar hypertrophy, but polyglecaprone was reported showing the highest rate of scar dehiscence after using intracutaneous butterfly suture technique.*
Samel et al. (12)	*The observational study showed that PGCL is a reliable, long-lasting material that the authors recommend for routine use in abdominal surgery*
Tang et al. (13)	*The authors judge laparoscopic choledochoduodenostomy using Monocryl for the closure as a safe and effective drainage procedure for the selected patient group with uncommon complications and promising postoperative results.*
Weber et al. (14)	*The authors recommend the use of the monofilament PGCL as a preferred suture for the combination of simultaneous buried and surface suture.*
Parell et al. (9)	*The authors conclude that Monocryl (PGCL) is ideally suited for use closure of facial skin wounds in the head and neck because it maintains strength for about 14 days and is well absorbed in about 30 days. It rarely extrudes or forms a suture abscess*

Javed et al. (15)	*Studies on oral tissue reactions to sutures have revealed constant inflammatory reactions, which are most prominent with silk and cotton and minimal with others including nylon, polyester, ePTFE, polyglecaprone 25 and PGA. Investigations on colonization on various intraoral suture materials from patients having undergone dentoalveolar surgery showed a larger numbers of bacteria on silk as compared to polyglecaprone 25.*
Vats and Pandit (16)	*poliglecaprone absorbable suture is associated with significantly less discomfort at the suture site after using for subcuticular skin stitches in post-cesarean women. Wound discharge is significantly less with poliglecaprone and polyamide comprared to other multifilament sutures.*
Yag-Howard et al. (17)	*In dermatologic surgery the absorbable monofilament poliglecaprone 25 can serve as the sole suture material in closing deep surgical defects involving subcutaneous and epidermal tissue with the benefits of providing aesthetically pleasing outcomes, increased versatility, ease of handling, and convenience.*
Odijk R et al. (18)	*Monocryl (poliglecaprone 25) is superior for intracotaneous closure of the skin in mediolateral episiotomies*
Sharma et al. (34)	*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. (35)	*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)*
As a result of the above mentioned publications the biocompatibility characteristics of the PGCL based surgical sutures can be considered as favourable for the use of this suture for tissue approximation respectively ligation.	

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. In the literature searches carried out until December 31, 2024, no new relevant literature with Assut AssuCryl® MonoRapid 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)

The complications and side-effects associated with PGCL absorbable surgical sutures are rare and are discussed in the above chapter for each of the identified clinical trials.

Patil and Duckett (19) reported complications after vaginal prolapse surgery which might be attributed to the suture material. Pelvic organ prolapse (POP) surgery can be associated with early postoperative morbidity resulting in significant service utilisation. This study aimed to investigate whether different suture materials cause different rates of early postoperative morbidity by comparing two cohorts using case–control methodology. A total of 100 women undergoing POP surgery with vaginal closure with Vicryl (polyglycolic acid) multifilament sutures were matched by operation with a cohort in which 2/0 Monocryl (poliglecaprone 25) monofilament sutures were used. The multifilament suture group had significantly higher rates of offensive discharge ($p < 0.001$), vaginal bleeding ($p < 0.001$) and vaginal pain ($p = 0.004$). They were more likely to receive medical advice (0.007). Size 1 multifilament sutures result in higher levels of postoperative morbidity when compared with 2/0 monofilament sutures.

Scheman et al (20) reported a single case of a suspected contact allergy to poliglecaprone 25 sutures. A 42-year-old woman who had a tattoo on the right wrist surgically removed 2 days prior developed severe erythema and swelling at the incision site. Exposure at the incision site was limited to bacitracin, poliglecaprone 25 suture, and plain cotton gauze. Patch testing of bacitracin was performed, which was ++ (moderately positive reaction) at the 96-hour reading, indicating that part of the reaction was due to the topical antibiotic. Testing of the suture was performed by tying the suture to the skin of the forearm and removing it at 48 hours. There was a ++ reaction to the suture prior to removal at 48 hours, which increased to +++ (severely positive reaction) after suture removal at 96 hours. Therefore, it appears that allergy to the suture also was partially responsible for the postsurgical reaction.

All published data about PGCL sutures show a good performance and safety of the absorbable monofilament material in the intended use. Only a few of the identified articles revealed side effect for sutures made of PGCL.

6.3.4 Clinical benefits

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

- AssuCryl® MonoRapid can be absorbed by the body without removing the thread
- A follow-up visit to remove the patient's sutures is not required and thus the possibility to of decreased scarring and infection is eliminated
- No foreign body left after complete absorption
- Save time
- Easy to handle
- High tensile strength
- Excellent pliability
- Smooth passage through tissue

6.4 Summary of clinical performance and safety

The evaluation of the clinical data for the absorbable surgical sutures made from polyglecaprone showed that there is sufficient clinical data that confirm the safety and the performance of the devices. The AssuCryl® MonoRapid absorbable surgical sutures can be considered as similar to other PGCL sutures 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 – here especially polyglecaprone 25 based surgical sutures - is huge since the 1990ies 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® MonoRapid absorbable sutures - as similar PGCL sutures - 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 PGCL are widely used since its introduction in 1994 in different types of surgery. The Assut product AssuCryl® MonoRapid complies with the state-of-the-art technical standard which is the European Pharmacopoeia Monograph 01/2008:0666. The product can be considered as comparable with similar PGCL sutures in the market. 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. The efficacy and safety of the products has been well-established.

The safety of the AssuCryl® MonoRapid absorbable 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.

The results obtained in the clinical evaluation confirm that the benefit outweighs the risks associated with the use of the AssuCryl® MonoRapid 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 in this clinical evaluation it is concluded that risk-benefit ratio for the AssuCryl® MonoRapid absorbable 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 demonstrate the safety and performance of the medical device. PMCF runs parallel with the processes 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® MonoRapid 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® MonoRapid (PGCL).
See table below with the rate (%) for AssuCryl® MonoRapid (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 MonoRapid (PGCL) undyed	07613406ACLMRPGCL25	10 511	1 131	8 026	6 461	7 542	33 671						0						
AssuCryl MonoRapid (PGCL) violet	07613406ACLMRPGCL25	1 651	6 092	2 094	1 807		11 644						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® MonoRapid, there was no complaint and no vigilance case between 2020 and 2024, rate = 0%; all risks associated to AssuCryl® MonoRapid 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.

Advantages and disadvantages of the different technical solutions such as surgical glues, staplers, zippers and surgical sutures are summarized in a review article (21).

Based on a yearly literature searches and analysis which is detailed in the Clinical Evaluation Report, the sutures AssuCryl®MonoRapid, 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 (Sandhya et al. (36)) becomes more relevant but there are still no all-encompassing therapeutic alternatives replacing surgical sutures in general.

Technical specifications for absorbable surgical sutures are described in the monographs of USP and European Pharmacopoiea (22). Both monographs define the suture sizes, breaking loads and strength of needle attachment. AssuCryl® MonoRapid complies with the requirements of the Pharm. Europ. Monograph.

8. Suggested profile and training for users

The AssuCryl® MonoRapid 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
Eur. Pharmacopeia Edition 11 (version 11.8)	Sterile synthetic absorbable sutures braided and monofilament	2025

10. Revision history

See above (top of document).

11. Literature

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