Assut sutures of Switzerland

Summary of Safety and Clinical Performance (SSCP)

Absorbable Surgical suture

AssuCryl® MonoSlow

CE-Mark since 2003

VERSION 06

24.07.2025

Assut Medical Sàrl
PO Box No. 5
CH-1009 Pully
Switzerland

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
PDO	Polydioxanone
O.R.	Operating Room
Glycoxylate	Organic molecule involved in metabolism

Revision history

Revision 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:

	Author	**Reviewed by**	**Released by**
Department:	MT Promedt Consulting Regulatory Affairs Manager	Assut Medical Sàrl Regulatory Affairs Manager	Assut Medical Sàrl CEO
Name:	Barbara Kathage	Catherine Baerfuss	Marc Baerfuss
Date:	24.07.2025	24.07.2025	24.07.2025
Signature:			

Table of Contents

1 Introduction

This summary of safety and clinical performance (SSCP)for the surgical absorbable suture AssuCryl® MonoSlow 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 excludes the italics part of the chapters 6.1, 6.1.1 and 6.3.1 to 6.3.3, 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® MonoSlow
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	07613406ACLMSPDOLC
Class of the device	Class 3, Rule 8, Annex VIII, MDR
Year when the device was CE-marked	2003
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 :** H0101010101 POLYDIOXANONE MONOFILAMENT

3 Intended use of the device

3.1 Intended purpose/intended use and indications/application

AssuCryl® MonoSlow monofilament sutures are intended for use in general soft tissue approximation and/or ligation. AssuCryl® MonoSlow should not be used in cases where an extended wound support over a period of 6 weeks is desirable.
AssuCryl® MonoSlow is suitable for every patient who complies with the intended purpose.
The suture material to be used is selected in accordance with the patient's condition, the surgeon's experience, the surgical procedure and the size of the wound.

3.2 Contraindications

AssuCryl® MonoSlow monofilament sutures, being absorbable, should not be used where extended approximation of tissues under tension beyond six weeks is required. The sutures should not be used either in conjunction with the implantation of prosthesis such as heart valves or synthetic grafts. AssuCryl® MonoSlow is not intended for use in cardiovascular surgery, microsurgery and neural tissue.

4 Device Description

4.1 Device description

AssuCryl® MonoSlow is a monofilament synthetic absorbable suture made of ≥ 99.9% of Polydioxanone and ≤ 0.1% of dye.
AssuCryl® MonoSlow 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® MonoSlow 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® MonoSlow meets all requirements established by the United States Pharmacopeia (USP) for absorbable surgical sutures and the European Pharmacopeia (Eur. Ph.) for synthetic monofilament absorbable sterile sutures, current editions.

Once AssuCryl® MonoSlow 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® MonoSlow will occur by means of hydrolysis. The breakdown product 2-hydroxy-ethoxy-acetic acid will be metabolized by the body. Implantation studies indicate that the AssuCryl® MonoSlow monofilament suture material retains approximatively 80% of its initial strength after about

14 days and approximatively 50 % after about 28 days. Absorption begins as a loss of tensile strength followed by loss of mass and is essentially complete between 180 to 240 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® MonoSlow.

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. In the body, PDO is broken down into glycoxylate and excreted in the urine or converted into glycine and subsequently into carbon dioxide and water. PDO has demonstrated no acute or toxic effects on Implantation. 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® MonoSlow 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 orthopedic procedures, immobilization by external support may be employed at the discretion of the surgeon. In case of poor blood supply in the tissues, consideration should be given to delayed absorption time. This material may be inappropriate in elderly or malnourished or debilitated patients or in patients whose wounds heal slowly.

When using AssuCryl® Monoslow - 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

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.

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. The polydioxanone 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 (2).

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.

Comprised of the polyester poly (p-dioxanone), this monofilament represents a significant advance in suturing options. It combines the features of soft, pliable, monofilament construction with absorbability and extended wound support for up to 6 weeks. It elicits only a slight tissue reaction. This material is well suited for many types of soft tissue approximation, including paediatric cardiovascular, orthopedic, gynecologic, ophthalmic, plastic, digestive, and colonic surgeries. Like other synthetic absorbable sutures, PDS II Sutures are absorbed in vivo through hydrolysis. Approximately 70% of tensile strength remains 2 weeks post implantation, 50% at 4 weeks, and 25% at 6 weeks. Absorption is minimal until about the 90th day postoperatively and essentially complete within 6 months. The safety and effectiveness of PDS II sutures in microsurgery, neural tissue, and adult cardiovascular tissue have not been established. PDS II sutures are available clear or dyed violet to enhance visibility (Ethicon Manual, 3).

6.1.1 Degradation of absorbable surgical sutures (PDO)

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.

PDO sutures are monofilament sutures and already on the world market by different manufacturers since 1981 (4). PDO, having an ester linkage, is known for degradation by hydrolysis of ester linkage. 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. PDO is one of the slowest absorbable surgical sutures.

It retains the original strength for 50% after 4 weeks, and the substantially complete absorptions is after 6 months. Other authors report the half life tensile strength of the monofilament PDO to be about 6 weeks. 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.

Being an aliphatic polyester, PDO undergoes degradation by the nonspecific scission of the ester bond. In the body, PDO is broken down into glycoxylate and excreted in the urine or converted into glycine and subsequently into carbon dioxide and water. PDO has demonstrated no acute or toxic effects on implantation (2).

Monofilament synthetic absorbable suture materials offer excellent glide characteristics and cause minimal tissue trauma as a result of their smooth monofilament structure and gradual bio-absorption. An investigation was conducted on 72 rats to compare three types of monofilament absorbable suture material (Polydioxanone, Poliglecaprone 25, Glycomer 631), with respect to their clinical characteristics, tissue inflammatory reaction and suture absorption times. The results identified different qualities for each suture: Poliglecaprone 25 and Glycomer 631 suture materials were found to be less reactive than Polydioxanone in rat skin. However, because of their extremely low tissue reaction values, all three materials were deemed particularly suitable for use as intracuticular sutures (2).

There were strong indications from the studies performed by Salthouse et al. (5), that the products of suture hydrolysis are probably metabolized through the oxidative enzyme systems of cells adjacent to the suture. Summarizing literature articles describe the excellent biocompatibility and product safety (6) of the PDO based surgical sutures.

6.2 Clinical evidence for the CE-marking

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

6.3 Summary of clinical data from other sources

Poly (p-dioxanone) (PDO) sutures are monofilament sutures and introduced as PDS in 1980ies. Since its invention PDO based synthetic absorbable sutures are widely used around the world where prolonged wound 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® MonoSlow is a legacy device which is on the market since since 2003, 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 PDO in general soft tissue approximation and/or ligation

In the following results of different studies that are summarized, that provide information on Poly (p-dioxanone) mostly the Assucryl® Monoslow to similar PDO sutures in clinical use.

PDO 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 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 (2).

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 PDO in general soft tissue approximation and/or ligation. If the studies refer to the use of a specific PDO (PDS) suture, the brand name is mentioned, even if these are not equivalent devices but only similar devices.*

Reference	***Content***
Ratner et al. (7)	*PDS is described as useful as a buried cutaneous suture in situations requiring increased wound strength for a longer period of time decreased tendency to produce suture abscesses and it tends not to cut through tissue, unlike Vicryl and Dexon.*
Sajid et al. (8)	*PDS and Prolene/Nylon are equally effective for the closure of abdominal fascia following laparotomy*
Murtha et al. (9)	*Cosmesis scores, rates of infection, dehiscence, and other adverse events as well as closure time and pain scores were comparable between barbed suture and polydioxanone suture used in women undergoing caesarean.*
Bigdelian et al. (10)	*The authors conclude that sternal closure with the polydioxanone suture in combination with figure-of-eight technique is a safe and suitable method in children with good clinical results*

Ohira et al (11)	*Surgical sutures included were Polysorb and PDS II used in patients undergoing elective laparotomy through a midline vertical incision for gastric or colon cancer surgery. No significant difference between short-term and long-term tensile strength was reported.*
Matthews et al. (12)	*Mesh and permanent suture exposure rates in the first year after minimally invasive total hysterectomy and sacrocolpopexy with a lightweight polypropylene or delayed absorbable (PDS)) sutures. Although there is no significant difference between the two groups the adsorbable PDS suture seems to cause a little less problems.*
Ghafoor et al. (13)	*The development of incisional hernia and length of hospital stay post-operatively due to wound closure after midline incisional laprotomy was considerably reduced in the polydioxanone group in comparison to polypropylene group*
As a result of the above-mentioned publications the biocompatibility characteristics as well as knot security and low rate of suture abscesses of the PDO material can be considered as favourable for the use of this suture for tissue approximation respectively ligation	

Application of PDO in gastrointestinal surgery

***Table 2**: Summary of results of different clinical studies, trials and investigations regarding the use of PDO in gastrointestinal surgery*

Reference	***Content***
Niggebrugge et al (14)	*A comparison of the laparatomy closure with interrupted polyglactin 910 and continuous polydioxanone showed no difference between the two investigated suture materials with regard to the incidence of burst abdomens.*
Hilgert et al (4)	*The authors concluded, that the recurrence rate in using PDS and Prolene for Shouldice repair of primary inguinal hernias were higher than expected, but there was no difference between the two groups.*
Gillatt et al. (15)	*The use of PDS (Ethicon) suture in gastrointestinal surgery was investigated and no problems were encountered with PDS when used for gastric and small bowel surgery and it is a suitable alternative to chromic catgut but it may be inappropriate to use PDS alone for left colonic anastomoses.*
Summarizing the results of the above-mentioned publications the biocompatibility and other characteristics of the PDO material can be considered as mostly favourable for the use of this suture gastrointestinal surgery.	

Application of PDO in dermatology

Coras et al (19) compared two absorbable monofilament polydioxanone threads (PDS II and Serasynth) in intradermal buried sutures. The main objective of this comparing test was to evaluate the intraoperative handling qualities, scar dehiscence and possible side effects. Therefore in 30 excisions, half of each suture was performed with PDS II, whereas the other half was closed with Serasynth. Clinical evaluation for scar spreading, spitting of the sutures, hypertrophic scarring, or suture granuloma was performed 3 and 6 months after surgery. The results obtained showed no significant difference in scar spreading, hypertrophic scarring, or the incidence of suture granuloma. A significantly lower frequency of spitting was seen with Serasynth than with PDS II. The handling and suturing properties of Serasynth were estimated to be slightly superior compared with those of PDS II. The authors concluded, that PDS II and Serasynth provide equal cosmetic results when applied in an appropriate suturing technique. Possibly owing to its better pliability, the frequency of spitting was lower with Serasynth.

6.3.2 Current appraisal of literature for absorbable sutures

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.

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 study of Sheetrit et al (2009) (20), the goal was to evaluate the invention related to a prosthetic for repairing an opening or a defect in a soft tissue, to its preparation and use. In each rat, the mesh was applied on the abdominal wall defect and attached to the area by two opposite and in-diagonal Sutures using 5-0 Assucryl® MonoSlow suture (AssutSutures, Switzerland). Following the mesh implantation the animals were monitored daily for assessing any irritation or pain signs.

In the case study from Romanescu et al (2021) (21) a 45-year-old right hand dominant male with a circular saw trauma at his right hand, with complex bone and soft tissue defect of the first metacarpal ray was treated. The patient was daycare-hospitalized for the first step of EPLT reconstruction with Wright Medical Hunter Tendon Rod 2 mm x 24.5 attached by the remaining tendon distal and proximal heads with 4-0 nonabsorbable suture monofilament, followed by EPLT reconstruction with extensor digitorum longus tendon graft of the 2nd toe at around 6 weeks after the spacer's implantation - Pulvertaft technique (3-0 Assucryl® Monoslow suture). The patient started active rehabilitation one week after the tenoplasty. At 6 months follow-up, there was evidence of good results, with 40% regained range of motion (ROM) in active flexion and extension of the thumb, good favorable functional prevention and no cold induced pain.

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

***Table 3**: Summary of complications and side-effects associated with polydioxanone absorbable surgical sutures*

Reference	***Content***
Torre et al (16)	*One observed case an allergic reaction on PDS II in a patient with arthrodesis of the right wrist. Here the patient developed pruritus and erythema in the site of the wound.*
Kuduban et al. (17)	*Polydioxanone suture material, which is absorbed in 6 months, is commonly used for nasal tip surgery and caused a skin reaction in a 25-year-old male patient who underwent endonasal septorhinoplasty procedure with endo-tracheal general anesthesia.*
Ruiz-Tover et al. (18)	*The results show first indications on a reduced risk of Surgical site infections due to the use of antimicrobial-coated suture (PDS Plus), but since there are no further clinical investigations with an appropriate high quality conventional synthetic adsorbable suture with its relatively low tissue reaction (PDS) remains to be the first choice among available sutures.*
The literature search for did not identify any new side-effects or unknown risks associated with the use of absorbable monofilament PDS sutures. Thus, a very positive safety profile of the well-established absorbable monofilament PDS material can be concluded.	

6.3.4 Clinical benefits

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

- AssuCryl® MonoSlow can be absorbed by the body without removing the thread
- A follow-up visit to remove the patient's sutures is not required and consequently reduces the possibility of scarring and infection
- No foreign body left after complete absorption
- Save time
- Easy to handle
- High initial 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 polydioxanone (PDO) showed that there is sufficient clinical data that confirm the safety and the performance of the devices. The Assucryl® MonoSlow absorbable surgical sutures can be considered as similar to other PDO sutures in the market as they are made from PDO material, 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 made from PDO is huge since the 1980ies and the application of the absorbable surgical sutures is part of the general surgical procedures especially where prolonged maintenance of the tensile strength is required.

Severe complications with absorbable surgical sutures and here sutures made from PDO (polydioxanone) are uncommon.

The Assucryl® MonoSlow absorbable surgical 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 polydioxanone (PDO) are widely used since its introduction in 1980 in different types of surgery. The Assut product Assucryl® MonoSlow 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 the similar devices. No further risks are generated.
The use of absorbable surgical sutures – here sutures made from PDO - can be considered as the state-of-the-art technology for surgical wound closure where prolonged maintenance of tensile strength is required. The efficacy and safety of the products has been well-established and documented in the literature review.

The safety of the Assucryl® MonoSlow 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 for absorbable surgical sutures made from PDO.

The results obtained in the clinical evaluation confirm that the benefit outweighs the risks associated with the use of the Assucryl® MonoSlow 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® MonoSlow 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 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® MonoSlow 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® MonoSlow (PDO).
See table below with the rate (%) for Assucryl® MonoSlow (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 MonoSlow (PDO) violet	07613406ACLMSPDOLC	26 032	20 841	29 603	21 614	24 802	122 892						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® MonoSlow, there was no complaint and no vigilance case between 2020 and 2024, rate = 0%; all risks associated to Assucryl® MonoSlow 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, staples, zippers and surgical sutures are summarized in a review article (19).

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. 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® MonoSlow, under evaluation as conventional sterile synthetic absorbable sutures, remains to be the state-of-the-art wound closure techniques. During the last years using a triclosan coating to reduce surgical site infections (Depuydt et al. (23)) becomes more relevant but there are still no all-encompassing therapeutic alternatives replacing surgical sutures in general.

8 Suggested profile and training for users

The Assucryl® MonoSlow 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

1. Suzuki S. and Ikada Y. Sutures for wound closure, in: Biomaterials for surgical operations, Chapter 8, p 189-197, Springer, 2011
2. Pillai CK, Sharma CP. Review paper: absorbable polymeric surgical sutures: chemistry, production, properties, biodegradability and performance. J. Biomater Appl 25, 291-366, 2010
3. Ethicon Wound Closure Manual, undated
4. Hilgert E et al., Comparison of polydioxanone (PDS) and polypropylene (Prolene) for shouldice repair of proimary inguinal hernias: a prospective randomized trial Eur J Surg 1999, 165: 333-338
5. Salthouse,T.N., Matlaga B.F.: Polyglactin 910 suture absorption and the role of cellular enzymes. Surg Gynecol Obstet 142:544-550, 1976
6. Chu, C.C.: Survey of clinically important wound closure material, in: Biocompatible polymers, Metals and Composites, M.Szycher (ed), Chapter 22, pp. 477-527, Technomic Publishing, Lancaster, USA, 1983,
7. Ratner D., Nelson BR., Johnson TM.: Basic suture materials and suturing techniques Semin Dermatol. 13:20-26, 1994
8. Sajid M.S., Parampalli U., Baig MK, McFall MR.: A systematic review on the effectiveness of slowly-absorbable versus non-absorbable sutures for abdominal fascial closure following laparotomy. Int J Surg 9, 615-625, 2011
9. Murtha AP, Kaplan AL, Paglia MJ, Mills BB, Feldstein ML, Ruff GL. Evaluation of a novel technique for wound closure using a barbed suture. Plastic and Reconstructive Surgery 2006;117(6):1769–80
10. Bigdelian H., Mohsen Sedighi M., Evaluation of sternal closure with absorbable polydioxanone sutures in children. J Cardiovasc Thorac Res, 2014, 6(1), 57-59
11. Ohira G., Kawahira H., Miyauchi H., Suzuki K., Nishimori T., Hanari N., Mori M., Tohma T., Gunji H., Horibe D., Narushima K., Matsubara H. Surg Today (2015) 45:841–845
12. Matthews CA, Geller EJ, Henley BR, Kenton K, Myers EM, Dieter AA, Parnell B, Lewicky-Gaupp C, Mueller MG, Wu JM. Permanent Compared With Absorbable Suture for Vaginal Mesh Fixation During Total Hysterectomy and Sacrocolpopexy: A Randomized Controlled Trial. Obstet Gynecol. 2020 Aug;136(2):355-364.
13. Ghafoor M, Butt MQ, Imtiaz A, Jamil A, Yaseen MS, Laique T. Comparison between Polydioxanone and Polypropylene Sutures for Incisional Hernia during Midline Incisional Laprotomy Procedure among Pakistani patients PJMHS (Pakistan Journal of Medical & Health Sciences) Vol. 14, NO. 2, Apr – Jun 2020 682
14. Niggebrugge AH, Hansen BE, Trimbos JB, van de Velde CJ, Zwaveling A. Mechanical factors influencing the incidence of burst abdomen. Eur J Surg 1995, 161: 655-661
15. Gillatt DA, Corfield AP, May RE, Bartolo DC, Leaper DJ. Polydioxanone suture in the gastrointestinal tract. Annals of the Royal College of Surgeons of England. 1987 Mar;69(2):54-56
16. Della Torre FD, Della Torre E, De Berardino F., Side effect to polydioxanone. Eur Ann Allerg Clin Immunol 2005, 37(2): 47-48
17. Kuduban O., Kuduban SD. Early Skin Reaction of Polydioxanone Suture Material Following Septorhinoplasty. Am J Case Rep, 2015; 16: 276-278
18. Ruiz-Tovar J, Llavero C, Jimenez-Fuertes M, Duran M, Perez-Lopez M, Garcia-Marin A. Incisional Surgical Site Infection after Abdominal Fascial Closure with Triclosan-Coated Barbed Suture vs Triclosan-Coated Polydioxanone Loop Suture vs Polydioxanone Loop Suture in Emergent Abdominal Surgery: A Randomized Clinical Trial. J Am Coll Surg. 2020 May;230(5):766-774.
19. Al-Mubarak L., Al-Haddab M., Cutaneous Wound Closure Materials: An Overview and Update, J Cutan Aesthet Surg. 6, 178–188, 2013
20. Sheetrit E, et al. Implantable device comprising a substrate pre-coated with stabilized fibrin. Patent US 20100076464 A1. Pub date Mar. 25, 2010
21. Romanescu V, et al. “The “EVE” Procedure - Vascularized Serratus and Rib Free Flap for First Metacarpal Reconstruction- A Case Report. Is it a Reliable Option for Metacarpal Bones Reconstruction?". Acta Scientific Orthopaedics 4.7 (2021): 35-37.
22. Pharm. Europ 01/2008:0666 Sutures sterile, synthetic absorbable monofilament
23. Depuydt M, Van Egmond S, Petersen SM, Muysoms F, Henriksen N, Deerenberg E. Systematic review and meta-analysis comparing surgical site infection in abdominal surgery between triclosan-coated and uncoated sutures. Hernia. 2024 Aug;28(4):1017-1027. doi: 10.1007/s10029-024-03045-5. Epub 2024 May 7. PMID: 38713430; PMCID: PMC11297069.