SUMMARY of SAFETY and CLINICAL PERFORMANCE (SSCP) for HEALTH CARE PROFESSIONNALS

A'LINK'S®

Foreword

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of main aspects of the safety and clinical performance of the device.

The SSCP is not intended to replace the Instructions For Use as the main document to ensure the safe use of the device, nor intended to provide diagnostic or therapeutic suggestions to intended users or patients

The following information is mainly intended to users (health care professionals such as surgeons). A summary intended for patients can be found at the end.

1. Device Identification and general information

1.1. Device Trade Name(s): **A'LINK'S®**

The medical device has also the following private labels: ARTHROFIX, FH ANCHORS – BIOABSORBABLE, COREFIX, S-Anchor, HC Link, Anc'Or, Eclipse A.

1.2. Manufacturer name and address(es):

TEKNIMED S.A.S.		
Headquarters 8, rue du Corps Franc-Pommiès 65500 Vic en Bigorre France	*Production and facilities* 11-12, rue d'Apollo - ZI de Montredon 31240 L'Union France	*Distribution site (labelling)* ZI de la Herray 65500 Vic en Bigorre France

1.3. Manufacturer's SRN (Single Registration Number): **FR-MF-000001224**

1.4. Basic UDI-DI: **376017704B16D7**

1.5. Medical device nomenclature description / EMDN nomenclature: **P09120102 – anchors, tendons and ligaments synthesis**

1.6. Class of device: **III**

1.7. Year when the first certificate (CE) was issued covering the device: **2014**

The medical device has been introduced for the first time in the following countries:

Country	Year of introduction
Europe	2014
Ukraine	2016
Vietnam	2016
Macedonia	2017
Brazil	2018
Uruguay	2018
Iran	2019
Lebanon	2019
Peru	2019
India	2019

Serbia	2020
Morocco	2020
Ecuador	2020
Malaysia	2021
South Africa	2021

1.8. Authorised representative if applicable; name and SRN: **NA** as the manufacturer is located in the EU.

1.9. NB's name (the NB that will validate the SSCP) and single identification number: **BSI Netherlands (CE 2797)**

2. Intended use of the device

1.1. Intended purpose

A'LINK'S® is a bioabsorbable suture anchor intended for repair or reinsertion of shoulder tendons.

2.2. Indication(s) and target population(s)

The A'LINK'S® Anchor device is indicated for rotator cuff repair.
The target population is: Adult patients presenting a rotator cuff tear.

2.3. Contraindications or restriction for use

- Procedures other than those stated in the INDICATIONS section.
- Benign bone pathologies (cysts) or acute osteopenia, which can compromise sound attachment of A'LINK'S.
- Proven infection or risk of infection.
- Patients susceptible to allergic reactions to the components and its products of metabolism.
- Due to non-sufficient available clinical evidence, the device is contraindicated in paediatric patients, and breast-feeding or pregnant women.

3. Device description

3.1. Description of the device

A'LINK'S® suture anchor is a bioabsorbable anchor mounted on a single-use inserter with two suture threads (round or tape), terminated or not with a suture needle.



Figure 1: Picture of A'LINK'S® anchor, inserter, and suture

Component	Composition	CAS#	Concentration
Anchor	PLA: Poly (70/30 ; L/DL) Lactide	52305-30-3	70%
	TCP: Tri Calcium Phosphate Ca3(PO4)2	7758-87-4	30%
White sutures (Round and tape)	Braided undyed (white) Ultra High Molecular Weight Polyethylene (UHMWPE) fibers	9002-88-4	100%
Blue sutures (Round and tape)	Braided undyed UHMWPE fibers	9002-88-4	98-100%
	Blue dye: Chromium-cobalt-aluminum oxide	68187-11-1	< 2%

White/Blue sutures (Round and tape)	Braided undyed (white) UHMWPE fibers	9002-88-4	87-88 %
	Braided blue UHMWPE fibers	9002-88-4	11-12%
	Blue dye is Chromium-cobalt-aluminum oxide	68187-11-1	< 2%
Surgical Needle	Stainless Steel	65997-19-5	97 - 100 %
	Medical grade silicone coating	71750-80-6	< 3%
Inserter	A'LINK'S 6.5 and 5.5: Stainless steel 316 L / 1.4404	NA	100%
	A'LINK'S 4.5: Stainless steel 630 / 1.4542	NA	100%
Handle	Polypropylene PPH 9020	9003-07-0	100%

Table 1: Composition of A'LINK'S® elements

The anchor is available in 4.5-, 5.5- and 6.5-mm diameter and preloaded with two ultra-resistant UHMWPE sutures. Sutures can be round or flat (tape). Round sutures can be loaded with needles.

A'LINK'S® suture anchor is available under the following references (legacy references in bold characters):

Reference	Device name	Size	Suture Type
T753155	**A'LINK'S**	**5.5**	- Blue thread (USP2) (Force Fiber®) - White thread (USP2) (Force Fiber®)
T753165	**A'LINK'S**	**6.5**	- Blue thread (USP2) (Force Fiber®) - White thread (USP2) (Force Fiber®)
T753145	A'LINK'S	4.5	- Blue thread (USP2) (Force Fiber®) - White thread (USP2) (Force Fiber®)
T753145R	A'LINK'S	4.5	- Blue thread (USP2) - White/Blue thread (USP2)
T753145F	A'LINK'S	4.5	- Blue Tape - White/Blue Tape
T753145M	A'LINK'S	4.5	- Blue thread (USP2) - White/Blue Tape
T753145N	A'LINK'S	4.5	- Blue thread (USP2) crimped at its extremities with 4 needles - White/Blue thread (USP2) crimped at its extremities with 4 needles
T753155R	A'LINK'S	5.5	- Blue thread (USP2) - White/Blue thread (USP2)
T75315F	A'LINK'S	5.5	- Blue Tape - White/Blue Tape
T75315M	A'LINK'S	5.5	- Blue thread (USP2) - White/Blue Tape
T75315N	A'LINK'S	5.5	- Blue thread (USP2) crimped at its extremities with 4 needles - White/Blue thread (USP2) crimped at its extremities with 4 needles
T753165R	A'LINK'S	6.5	- Blue thread (USP2) - White/Blue thread (USP2)
T753165F	A'LINK'S	6.5	- Blue Tape - White/Blue Tape
T753165M	A'LINK'S	6.5	- Blue thread (USP2) - White/Blue Tape
T753165N	A'LINK'S	6.5	- Blue thread (USP2) crimped at its extremities with 4 needles - White/Blue thread (USP2) crimped at its extremities with 4 needles

The device is delivered sterile and ready to be used.

3.2. Principles of operation of the device and mode of action

An anchor-receiving hole is generally first drilled in the bone at the desired point of tissue reattachment. Then a suture anchor is deployed in the hole using an appropriate installation tool. This effectively locks the sutures (generally 2 per anchor) to the bone, with the free end of the sutures extending out of the bone. Next, the soft tissue is moved into position over the deployed suture anchor. As this is done, the free ends of the sutures are passed through or around the soft tissue, so that each free end resides on the far side of the soft tissue. Finally, the sutures are used to tie the soft tissue securely to the bone.

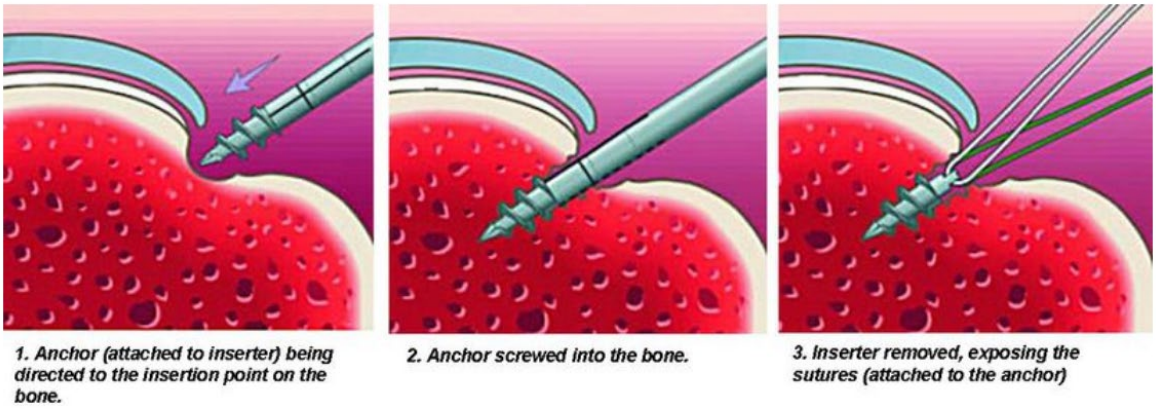


Figure 2: Suture anchor mechanism (Source: www.dolcera.com)

A'LINK'S® is a unique usage device.
Once implanted, the anchor is designed to be totally absorbed after an average of 4 years. This period may vary depending on the physiological condition of the patient.
The sutures are implantable, intended to support their function for 5 months.
The device is not intended to be removed and does not need any maintenance, unless a medical complication would require a surgery. Once in the body, the anchor is degraded in lactic acid which is metabolised and finally eliminated from the body as carbon dioxide and water.

3.3. Reference to previous generation(s) or variants if such exist, and a description of the differences

A'LINK'S® is not issued from any previous generation. It is available under various references depending on the size of the anchor and the type of the sutures as described above.

3.4. Description of any accessories which are intended to be used in combination with the device

A'LINK'S® is intended to be implanted using the Tap T06750X sold separately.

3.5. Description of any other device or products which are intended to be used in combination with the device

No other devices or products are intended to be used in combination with A'LINK'S® suture anchor.

4. Risks and warnings

4.1. Residual risks and undesirable effects

Complications usually encountered with bioabsorbable implants and reported in the scientific literature[1] (but no case reported with A'LINK'S®):

- Inflammatory reaction to foreign bodies, osteolysis, cyst formation, chondrolysis (with rates up to 26%e).
- Secondary tearing (with rates up to 20%).

[1] Sgroi M, Friesz T, Schocke M, Reichel H, Kappe T. 2019. *Biocomposite Suture Anchors Remain Visible Two Years After Rotator Cuff Repair*. Clin Orthop Relat Res 477, 1469–1478.

Other side effects, observed in a clinical study with A'LINK'S®, include:

- Capsulitis (5 cases, 5%)
- Transient post-operative pain (3 cases, 3%)
- Superficial infection (1 case, 1%)

Any serious incident occurring in relation to the device must be reported without delay to TEKNIMED and the competent local authority where the user and/or the patient is established.

4.2. Warnings and Precautions

Read instructions for use carefully prior to use and follow preparation and handling instructions of A'LINK'S®.
Ignoring the instructions for use may lead to potential undesirable effects.
For an optimum use of the device, it is essential to perform a thorough pre-operative review of the patient before the intervention in order to confirm the indication and plan the surgical technique.

Conservation

- It is strictly forbidden to re-sterilise the product. This product is supplied sterile unless package has been opened or damaged.
- This device is packaged and sterilised for single use only. Do not reuse, reprocess or resterilise. Reuse, reprocessing, or resterilisation may compromise the structural integrity of the device and/or lead to device failure which may result in patient injury or illness. Also, reprocessing or resterilisation of single use devices may create a risk of contamination and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another.
- Before use, check the protective wrapping carefully to ensure that it has not been opened nor damaged in a way that could affect its sterility.
- Do not use this product after the expiration date printed on the package.

Use

- Examine the product visually to identify any defects such as crack or deformation. Do not implant products with defects.
- When removing the product from its wrapping, be sure to follow asepsis rules.
- If packaging is unintentionally opened before use or damaged, do not use the product.
- Use the device accessories during the procedure. All other instruments are not recommended.
- Insert the tap without exceeding the indicated depth. Ensure axial alignment when inserting the anchor.
- Pulling too hard on the sutures can tear out or damage the anchor.
- Do not apply excessive or abrupt traction to the suture, as this may cause the needle uncrimping.

4.3. Other relevant aspect of safety, including a summary of any field safety corrective action (FSCA) if applicable

No FSCA have been issued for A'LINK'S® or any private label.

5. Summary of clinical evaluation and relevant information on post-market clinical follow-up (PMCF)

5.1. Summary of clinical data related to equivalent device, if applicable

New references for A'LINK'S® (listed in section 3.1. above) are demonstrated to be equivalent to the A'LINK'S® legacy references (also listed in section 3.1.), all of them manufactured by Teknimed, under the same basic UDI-DI (376017704B16D7) and sharing the same current version of Summary of Safety and Clinical Performance (SSCP) which will be made available on Eudamed when the later will be functional.
As detailed in section 5.3 below, clinical data collected on the A'LINK's® equivalent legacy devices, up to 4 years after the surgery, confirmed that rotator cuff repair with A'LINK'S anchors can reliably improve both shoulder pain and function. Radiological analysis confirmed bone remodelling and reconstruction around the anchor. No side effects, no complications directly related to the anchor were reported.

5.2. Summary of clinical data from conducted investigations of the device before the CE-marking, if applicable

Non applicable. No clinical investigations have been conducted on the device before the CE-marking.

5.3. Summary of clinical data from other sources, if applicable

Performance and safety of A'LINK'S® suture anchors were also evaluated through clinical studies:
A first PMCF study performed in 2014 when the product was first marketed.
Title: Post-Market Follow-up – A'LINK'S®
Identity of the device: A'LINK'S® suture anchor

Population: 25 patients (n=20 (80%) men; n=5 (20%) women) were included and followed for an average of 20 months (12-20 months). Mean age was 54.9 years, with 78% of patients (n=15) between 50 and 59 years. Active patients represent 80% (n=20) patients.

Indications: Aetiologies were pain and decreased shoulder function that did not respond to conservative treatment. Indications for surgery were: 17 single wide ruptures of the supraspinatus; 3 partial ruptures of the supraspinatus; 3 ruptures of supraspinatus and infraspinatus; 3 ruptures of supraspinatus and subscapularis.

Surgery procedures: Anchors were implanted on the lateral side of the tuberosity to cover the footprint area and maximise the surface area and healing potential. A biceps tenotomy followed by a tenodesis was performed in 8 (32%) of patients. Installation was simple, after a quick use of the tap, A'LINK'S® anchors were implanted without difficulties.

Clinical outcomes: Overall, patients experienced a significant improvement of pain (VAS) and function (ASES score). The shoulder function (strength and range of motion evaluated by the ASES score), improved postoperatively, with a gain of 50 points at Postop vs Preop, whatever the tear size. The level of activity improved also. Driving was possible again after an average of 2.5 months and the return to work after 5 months.

Radiological outcomes: At 6 months follow-up, the anchors could still be easily identified, without signs of absorption. This is expected because the anchors must ensure adequate mechanical properties at that delay. After 1 year, anchor hydrolysis and bone reconstruction started to be visible at the anchor implantation sites. No signs of osteolysis, no inflammatory responses, no ruptures of the anchor or of the sutures were observed.

Safety: Only 1 nonserious adverse event was reported: a case of reflex sympathetic dystrophy in a particularly stressed young woman, aged 32. No (0%) postoperative complications related to the device were observed. No infection, no postoperative hematoma was reported.
Conclusion: The clinical results of this study confirm that arthroscopic rotator cuff repair can reliably improve both shoulder pain and function, regardless of the tear size. The advantage of using PLA-TCP composite anchor was demonstrated as the osteoconductive nature of these anchors allows absorption with full bone reconstruction without any side effects or complications. Radiological follow-up confirmed the bone remodelling and reconstruction around the anchor. No side effects, no complications directly related to the anchor were reported. No dissociation phenomenon, rejection, or consolidation problems were reported.

5.4. Overall summary of the clinical performance and safety

A'LINK'S® is a device issued from a well-known technology which has been used in orthopaedic surgeries for many years. It allows successful shoulder rotator cuff tendons repair, leading subsequently to clinical benefits for the patients such as pain alleviation and improvement in quality of life. Claims for performance and safety of A'LINK'S® have been verified and confirmed through Post-Market Clinical Follow-up (PMCF), and Clinical Evaluation:

		Literature	**Similar device**	**PMCF conducted in 2014**	**PMCF currently conducted**
Performance criteria	Restoration of function	≥ 50% at 2-year FU	≥ 50% at 2-year FU	ASES score: + 50 points at 2-year FU versus Preop	Pain: 0% painful patients at 4-year FU
	Patient satisfaction	≥ 90% at 2-year FU	≥ 90% at 2-year FU		100% satisfied patients with their health condition at 4-year FU
Safety criteria	Rate of bone reaction (osteolysis,	< 3% at 2-year FU	< 20% (grade > 2) at 2-year FU	0% at 2-year FU	0% at 4-year FU

	bone cyst, chondrolysis)				
	Rate of anchor failure (anchor pull-out, retear) t	< 5% at 2-year FU	< 30% at 2-year FU	0% at 2-year FU	0% at 4-year FU

No new or unexpected risks were identified during Post-Market Surveillance (PMS) or PMCF. The residual risks reported from the clinical studies (capsulitis, postoperative pain and superficial infection) are not related to the device itself but to the surgical procedure.
Therefore, considering the clinical benefits on pain and quality of life, as documented in the PMCF, versus the low level of residual risks, the overall benefit-risk balance of A'LINK'S® can be considered acceptable for the patients.

5.5. On-going or planned post-market clinical follow-up

Teknimed is currently conducting a post-market clinical follow-up which will confirm performance, safety and usability for all the Teknimed range of Sports products, including A'LINK'S®.
Title: Safety and performance assessment of sport surgery products - A Post-Market Clinical Follow-Up
Justification/Context: TEKNIMED has developed several devices currently used in orthopaedic surgery. With the increasing use of these procedures, there is a need for real-life long-term safety and efficacy data on these products.
Objective: The objective is to collect immediate, medium and long-term data after surgery, on the related clinical functional and complications outcomes of market-approved TEKNIMED Sports products to confirm their performance and safety in a real-world setting.
Study design: global, single arm, non-controlled, multi-centric, ambispective observational study. Patients will be followed as per local standard medical practices of the investigational sites. Data will be collected pre-operatively, at surgery and at standard of care follow-up (FU) visits.
Performance endpoints: Evaluation of pain, quality of life, and patients' satisfaction; radiological evaluation
Safety endpoints: Adverse events will be documented during the study and categorized as whether they are serious and whether they are related to the TEKNIMED device.
Statistical Analysis: Statistical analyses will primarily be descriptive as no hypotheses are enunciated to be demonstrated. Each outcome will be reported for each product separately, however, some products may be grouped and summarized if the products are related and if needed (e.g. cement + injection system). There are no intentions to compare or test data across products unless requested for a publication or other clinical evidence need. Should this later case occur, analytical analyses would be performed. According to the multiplicity of the explored parameters, the results of the statistical tests will have to be considered only as an exploratory basis. When needed, Kaplan-Meier survivorship analyses will be performed for several endpoints such as implant revision or aseptic loosening.

An interim analysis has been performed in November 2022, providing the following results:
Population: 102 patients (mean age 60.7-year, min 29 – max 83) were enrolled in the study at the time of this interim report. The majority of the cohort (95%, n=95) suffered from a shoulder rotator cuff tear, mainly of non-traumatic origin (68%, n=65).
Surgery procedures: A total of 234 anchors were used in this study: 2/3 of the surgeries (n=67; 65.7%) required the use of more than 1 anchor, mainly 2 (n=24; 23,5%) or 3 (n=26; 25.5%), and up to 5 anchors. All surgeries were performed using the Teknimed associated awl & tap of the A'LINK'S Instrumentation. All phases of use of A'LINK'S and its associated instrumentation were reported as 'Easy' by the investigators. No perioperative complications were reported.
Clinical outcomes:
- Pain: Before surgery, all subjects reported pain, with a mean level of 4,05 ±1,13 (Min=1; Max=6) on a 0 to 10 VAS. At the short-term FU visit (1,17 months ±0,47 post-surgery), pain level decreased to a mean 1,53 ±1,62 (Min=0; Max=6). At the medium-term FU visit (4.21 months ±1.46 post-surgery), pain level kept decreasing down to 0,51 ±1.17 and no patients reported pain at long-term FU visit (42.58 months ±14.43 post-surgery). Before surgery, 52% (n=51) of the cohort reported a consumption of antalgic and 45.9% (n=45) none. At the following visits, the trend decreased, with 100% subjects reporting no antalgic consumption at the long-term FU visit.

- Patients' well-being and satisfaction: Most of patients at the short-term FU visit (69,47%), and then 100% of patients at the long-term FU visit, considered that their health condition had improved after the surgery. Patients' quality of life was improved after surgery from the mid-term follow-up visit (4.21 months ±1.46 post-surgery).

Safety: 9 non serious adverse events were observed during the clinical follow-up:

- 5 cases of capsulitis which required no treatments. Indeed, capsulitis is a typical well-known complication, observed during or at the end of the postoperative immobilisation period. It will disappear naturally with the rehabilitation protocol and the subsequent softening of the shoulder. All these events resolved without sequelae.
- 3 cases of transient postoperative pain in the operated shoulder. 1 case required treatment by medication (pain killer). The subjects were asked to perform their rehabilitation protocol until the end, as the painful sensation could disappear with the softening of the shoulder. 2 of these events resolved without sequelae and 1 was still ongoing at last visit performed with the subject.
- 1 case of superficial infection in the operated shoulder due to procedure, treated with local antibiotic. This event is an anticipated event of the procedure, and resolved without sequelae in less than a month.

All adverse events were qualified as "not related" to the device, but their relatedness to the procedure was qualified as "Possible" or "Probable", and even "Definite" for the superficial infection.

Conclusions: This analysis of retrospectively enrolled patients aimed to evaluate short- and long-term safety and efficacy of a bioabsorbable anchor: A'LINK'S®, intended to be used in rotator cuff repair by arthroscopy procedures. Pain and complications were the main criteria assessed in the cohort of 102 patients, representing 234 implanted anchors, up to 42.58 months ±14.43 post-surgery.

During the surgery procedure, no adverse events or complications related to A'LINK'S® and its associated instrumentation (tap), and no implant failure were observed. The investigators' opinion on their easiness of use was favourable, confirming the satisfactory usability of A'LINK'S and its associated instrumentation.

Postoperative follow-up of patients demonstrated that pain was clearly improved after the surgery from a level of 4.05 ±1.13 at baseline to a level of 1.53 ±1.62 at the short-term FU visit (1.17 months ±0.47 post-surgery). Furthermore, most of patients at the short-term FU visit (69.47%), and then 100% of patients at the long-term FU visit, considered that their health condition had improved after the surgery. All these clinical outcomes allow to confirm the effectiveness of the use of A'LINK'S® in rotator cuff repair.

During the postoperative follow-up, no Serious Adverse Events were observed. 9 complications were reported, of which none was declared related to the device. All these adverse events are known and expected in this kind of surgical procedure. Two of these AE required treatment (medication) other than usual postoperative rehabilitation protocol prescribed after each surgery. These outcomes confirm the safety of use of A'LINK'S®.

To conclude, this long-term outcome analysis demonstrated that A'LINK'S® is an effective and safe device relevant to be used in shoulder rotator cuff repair procedures, including long head of biceps tenodesis.

6. Possible diagnostic or therapeutic alternatives

Clinical practice guidelines have been developed to assist healthcare professionals in the decisions making about appropriate health care for the treatment of rotator cuff disorders in adults. However, no consensus exists on the optimal treatment of rotator cuff diseases[2],[3]. Symptomatic small to medium full-thickness rotator cuff tears management has resulted in a notable improvement in patient-reported outcomes via both physical therapy and surgical management.

[2] Piper, C.C., Hughes, A.J., Ma, Y., Wang, H., Neviaser, A.S., 2018. Operative versus nonoperative treatment for the management of full-thickness rotator cuff tears: a systematic review and meta-analysis. J Shoulder Elbow Surg 27, 572–576. https://doi.org/10.1016/j.jse. 2017.09.032

[3] Khatri, C., Ahmed, I., Parsons, H., Smith, N.A., Lawrence, T.M., Modi, C.S., Drew, S.J., Bhabra, G., Parsons, N.R., Underwood, M., Metcalfe, A.J., 2019. The Natural History of Full-Thickness Rotator Cuff Tears in Randomized Controlled Trials: A Systematic Review and Meta-analysis. Am J Sports Med 47, 1734–1743. https://doi.org/10.1177/0363546518780694

According to HAS[4], medical treatment, such as oral medication, infiltration or physiotherapy is recommended as the first line of treatment in the management of degenerative rotator cuff tendon tears. The duration of the medical treatment varies depending on clinical, general and morphological elements. Following pharmacological treatments may be recommended to decrease pain: non-steroidal anti-inflammatory drugs (NSAIDs), corticosteroid injections, anabolic androgenic steroids, hyaluronic acid injections, platelet-rich plasma injection, prolotherapy injection, medicinal signalling cells, polydeoxyribonucleotide or glyceryl trinitrate.

Non-surgical/non-pharmacological conservative treatments are also part of the primary management options to improve pain and function of the shoulder. Rotator cuff tears can undergo a period of conservative management before considering surgery. The following non-surgical/non-pharmacological therapies exist to avoid surgery: physiotherapy, exercise, extracorporeal shock wave therapy, acupuncture, kinesio taping or microwave diathermy.

Finally, combining physical therapy and surgical management is recommended based on “strong evidence” by the AAOS Clinical Practice Guideline Summary[5].

7. Suggested profile and training for users

Implantation of TEKNIMED products should only be performed in an adapted environment and by qualified operators (orthopaedic surgeons) having a sound knowledge and full mastery in preparation techniques specific to TEKNIMED products. Preparation techniques may be acquired from the distributors qualified by TEKNIMED. The operator is responsible for any complications or harmful consequences which might result from an erroneous indication or operative technique, an improper use of the equipment and/or a failure to comply with the safety rules provided in the instructions for use. Neither TEKNIMED as manufacturer nor the authorized TEKNIMED representative can be held responsible for these complications.

8. Reference to any harmonized standards and CS applied

Standard reference	Standard revision	Standard title	Applicability
> General standards			
EN ISO 13485	2016/ A11: 2021	Medical devices - Quality management systems - Requirements for regulatory purposes	Fully whenever applicable
EN ISO 14630	2012	Non-active surgical implants - General requirements	Fully whenever applicable
EN ISO 14971	2019 / A11: 2021	Medical devices - Application of risk management to medical devices	Fully whenever applicable
EN 62366	2015 / A1:2020	Medical devices – Application of usability engineering to medical devices	Fully whenever applicable
XP S99-223	2020	Medical Device – Benefit / Risk management	Fully whenever applicable
EN ISO 14155	2020	Clinical investigation of medical devices for human subjects — Good clinical practice	Fully whenever applicable
> Product standards			
ISO 2859-1	1999 / A1: 2011	Sampling procedures for inspection by attributes — Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection	Fully whenever applicable

[4] HAS, 2008. Prise en charge chirurgicale des tendinopathies rompues de la coiffe des rotateurs de l’épaule chez l’adulte [www Document]. Haute Autorité de Santé. URL https://www.has-sante.fr/jcms/c_658445/fr/prise-en-charge-chirurgicale-des-tendinopathies-rompues-de-la-coiffe-des-rotateurs-de-l-epaule-chez-l-adulte (accessed 9SEP22).

[5] Weber, S., Chahal, J., 2020. Management of Rotator Cuff Injuries. JAAOS - Journal of the American Academy of Orthopaedic Surgeons 28, e193. https://doi.org/10.5435/JAAOS-D-19-00463

ISO 13781	2017	Implants for surgery - Homopolymers, copolymers and mixtures on poly (lactide) -- In vitro degradation testing	Fully whenever applicable
EN ISO 14602	2011	Non-active surgical implants — Implants for osteosynthesis — Particular requirements	Fully whenever applicable
ASTM F1088	2023	Standard Specification for Beta-Tricalcium Phosphate for Surgical Implantation.	Fully whenever applicable
ASTM F1925	2022	Standard Specification for Semi-Crystalline Poly(lactide) Polymer and Copolymer Resins for Surgical Implants	Fully whenever applicable
ASTM F2502	2017	Standard Specification and Test Methods for Bioabsorbable Plates and Screws for Internal Fixation Implants	Fully whenever applicable
ASTM F2503	2023	Standard Practice for Marking Medical Devices and other items for safety in the Magnetic Resonance Environment	Fully whenever applicable

> Biocompatibility standards

EN ISO 10993-1	2020	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process	Fully whenever applicable
EN ISO 10993-2	2022	Biological evaluation of medical devices — Part 2: Animal welfare requirements	Fully whenever applicable
EN ISO 10993-3	2014	Biological evaluation of medical devices — Part 3 Tests for genotoxicity, carcinogenicity and reproductive toxicity	Fully whenever applicable
EN ISO 10993-5	2009	Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity	Fully whenever applicable
EN ISO 10993-6	2016	Biological evaluation of medical devices — Part 6: Tests for local effects after implantation	Fully whenever applicable
EN ISO 10993-9	2021	Biological evaluation of medical devices — Part 9: Framework for identification and quantification of potential degradation products	Fully whenever applicable
EN ISO 10993-10	2021	Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization	Fully whenever applicable
EN ISO 10993-11	2018	Biological evaluation of medical devices — Part 11: Tests for systemic toxicity	Fully whenever applicable
EN ISO 10993-12	2021	Biological evaluation of medical devices — Part 12: Sample preparation and reference materials	Fully whenever applicable
EN ISO 10993-13	2010	Biological evaluation of medical devices — Part 13: Identification and quantification of degradation products from polymeric medical devices	Fully whenever applicable
EN ISO 10993-17	2009	Biological evaluation of medical devices — Part 17: Establishment of allowable limits for leachable substances	Fully whenever applicable
EN ISO 10993-18	2020/ A1:2022	Biological evaluation of medical devices — Part 18: Chemical characterization of medical device materials within a risk management process	Fully whenever applicable
EN ISO 10993-23	2021	Biological evaluation of medical devices — Part 23: Tests for irritation	Fully whenever applicable

> Labelling and packaging standards

EN ISO 14698-1	2003	Cleanrooms and associated controlled environments — Biocontamination control — Part 1: General principles and methods	Fully whenever applicable
EN 556-1	2001 / AC:2006	Sterilization of medical devices. Requirements for medical devices to be designated "STERILE". Part 1 : requirements for terminally sterilized medical devices	Fully whenever applicable
EN 868-7	2017	Packaging for terminally sterilized medical devices — Part 7: Adhesive coated paper for low temperature sterilization processes — Requirements and test methods	Fully whenever applicable

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	Fully whenever applicable
EN ISO 11607-1	2020	Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems — Amendment 1	Fully whenever applicable
EN ISO 11607-2	2020	Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes — Amendment 1	Fully whenever applicable
EN ISO 15223-1	2021	Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. General requirements	Fully whenever applicable
EN ISO 20417	2021/COR: 2021-12	Medical devices — Information to be provided by the manufacturer	Fully whenever applicable
ASTM D 4169	2022	Standard Practice for Performance Testing of Shipping Containers and Systems	Fully whenever applicable
ASTM D 4332	2022	Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing	Fully whenever applicable
ASTM D 4728	2017	Standard Test Method for Random Vibration Testing of Shipping Containers	Fully whenever applicable
ASTM D 5276	2019	Standard Test Method for Drop Test of Loaded Containers by Free Fall	Fully whenever applicable
ASTM D 999	2008	Standard Test Methods for Vibration Testing of Shipping Containers	Fully whenever applicable
ASTM F 1929	2015	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration	Fully whenever applicable
ASTM D 6653 / D 6653 M	2021	Standard Test Method for Determining Compressive Resistance of Shipping Containers, Components, and Unit Loads 1	Fully whenever applicable
ASTM D6344	2004	Standard Test Method for Concentrated Impacts to Transport Packages	Fully whenever applicable
ASTM D642	2020	Standard Test Method for Determining Compressive Resistance of Shipping Containers, Components, and Unit Loads 1	Fully whenever applicable
ASTM F2096	2011	Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)	Fully whenever applicable

> Microbiology standards

EN ISO 11737-1	2018/ A1:2021	Sterilization of medical devices — Microbiological methods — Part 1: Determination of a population of microorganisms on products	Fully whenever applicable
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	Fully whenever applicable

> Sterilisation standards

EN ISO 11135-1	2014 / A1: 2019	Sterilization of health care products — Ethylene oxide — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices	Fully whenever applicable
EN ISO 10993-7	2008 / AC1: 2009	Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals	Fully whenever applicable

9. Revision history

Revision number	Date issued	Change description	Revision validated by the Notified Body
1.0	DEC 2022	Creation	☐ Yes, language: English ☑ No

1.1	MAR 2023	Modification following BSI Round1 of initial clinical review under MDR: - Precisions on rates in section 4.1. 'Residual risks and undesirable effects' - Performance outcomes added in section 5.1. 'Summary of clinical data related to equivalent device, if applicable' - Additional information in section 6. 'Possible diagnostic or therapeutic alternatives'	☐ Yes, language: English ☑ No
1.2	APR 2023	Modification following BSI Round2 of initial clinical review under MDR: - Rephrasing of residual risks and undesirable effects (§4.1.) - Rephrasing of the summary of clinical data related to equivalent device (§5.1.) - Addition of information on Possible diagnostic or therapeutic alternatives (§10)	☐ Yes, language: English ☑ No
1.3	MAY 2023	Modification following BSI Round2 of initial clinical review under MDR: - Rephrasing of the summary of clinical data related to equivalent device (§5.1. & 5.4.)	☑ Yes, language: English ☐ No
1.4	NOV 2023	Modification following BS1 Round 1 of initial technical review under MDR: - Update of Table 1 - Addition of lifetime of suture in § 3.2 - Addition of standards in § 8	☑ Yes, language: English ☐ No

A summary of the safety and clinical performance of the device, intended for patients, is provided on next page.

SUMMARY of SAFETY and CLINICAL PERFORMANCE (SSCP) for PATIENTS - English Version
A'LINK'S®

Document revision: 1.4
Date issued: NOV2023

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the device. The information presented below is intended for patients or lay persons. A more extensive summary of its safety and clinical performance prepared for healthcare professionals is found in the first part of this document.

The SSCP is not intended to give general advice on the treatment of a medical condition. Please contact your healthcare professional in case you have questions about your medical condition or about the use of the device in your situation. This SSCP is not intended to replace an implant card or the Instructions For Use to provide information on the safe use of the device.

1. Device Identification and general information

1.1. Device Trade Name: **A'LINK'S®**

The medical device has also the following private labels: ARTHROFIX, FH ANCHORS – BIOABSORBABLE, COREFIX, S-Anchor, HC Link , Anc'Or , Eclipse A.

1.2. Manufacturer name and address(es):

TEKNIMED		
Headquarters 8, rue du Corps Franc-Pommiès 65500 Vic en Bigorre France	*Production and facilities* 11-12, rue d'Apollo - ZI de Montredon 31240 L'Union France	*Distribution site (labelling)* ZI de la Herray 65500 Vic en Bigorre France

1.3. Basic UDI-DI: **376017704B16D7**

1.4. Year when the device was first CE-marked: **2014**

2. Intended use of the device

2.1. Intended purpose

A'LINK'S® is an anchor with sutures. After healing, it is fully absorbed by the body. It is used to repair or reinsert shoulder tendons.

2.2. Indication(s) and intended patient groups

A'LINK'S® is used in shoulder surgery (rotator cuff repair)
A'LINK'S® is used on adults.

2.3. Contraindications

- Procedures other than those stated in the INDICATIONS section
- Bone disorder (benign bone pathologies (cysts) or low bone density (acute osteopenia)) which can result in bad attachment of the anchor
- Proven infection or risk of infection.
- Intolerance to constituents of the product (allergic reaction)
- Not enough data are available on some categories of patients. A'Link's® cannot be used in children. A'Link's® cannot be used in breast-feeding or pregnant women.

3. Device description

A'LINK'S® suture anchor is a bioabsorbable anchor mounted on a single-use inserter with two suture threads (round or tape), terminated or not with a suture needle.



Figure 3: Picture of A'LINK'S® anchor, inserter, and suture

Component	Composition	CAS#	Concentration
Anchor	PLA: Poly (70/30 ; L/DL) Lactide	52305-30-3	70%
	TCP: Tri Calcium Phosphate Ca3(PO4)2	7758-87-4	30%
White sutures (Round and tape)	Braided undyed (white) Ultra High Molecular Weight Polyethylene (UHMWPE) fibers	9002-88-4	100%
Blue sutures (Round and tape)	Braided undyed UHMWPE fibers	9002-88-4	98-100%
	Blue dye: Chromium-cobalt-aluminum oxide	68187-11-1	< 2%
White/Blue sutures (Round and tape)	Braided undyed (white) UHMWPE fibers	9002-88-4	87-88 %
	Braided blue UHMWPE fibers	9002-88-4	11-12%
	Blue dye is Chromium-cobalt-aluminum oxide	68187-11-1	< 2%
Surgical Needle	Stainless Steel	65997-19-5	97 - 100 %
	Medical grade silicone coating	71750-80-6	< 3%
Inserter	A'LINK'S 6.5 and 5.5: Stainless steel 316 L / 1.4404	NA	100%
	A'LINK'S 4.5: Stainless steel 630 / 1.4542	NA	100%
Handle	Polypropylene PPH 9020	9003-07-0	100%

Table 2: Composition of A'LINK'S® elements

The anchor is available in 4.5-, 5.5- and 6.5-mm diameter and preloaded with two ultra-resistant UHMWPE sutures. Sutures can be round or flat (tape). Round sutures can be loaded with needles.
The device is delivered sterile and ready to be used.

Principles of operation of the device and mode of action

An anchor-receiving hole is generally first drilled in the bone at the desired point of tissue reattachment. Then a suture anchor is deployed in the hole using an appropriate installation tool. This effectively locks the sutures (generally 2 per anchor) to the bone, with the free end of the sutures extending out of the bone. Next, the soft tissue is moved into position over the deployed suture anchor. As this is done, the free ends of the sutures are passed through or around the soft tissue, so that each free end resides on the far side of the soft tissue. Finally, the sutures are used to tie the soft tissue securely to the bone.

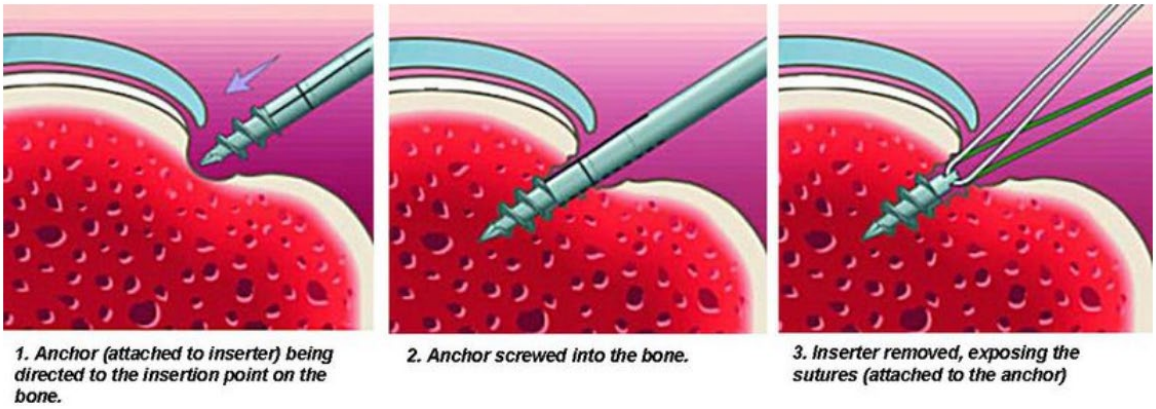


Figure 4: Suture anchor mechanism (Source: www.dolcera.com)

A'LINK'S® is a unique usage device.
Once implanted, the anchor is designed to be totally absorbed after an average of 4 years. This period may vary depending on the physiological condition of the patient.
The sutures are implantable, intended to support their function for 5 months.
The device is not intended to be removed and does not need any maintenance, unless a medical complication would require a surgery.

4. Risks and warnings

Contact your healthcare professional if you believe that you are experiencing side-effects related to the device or its use or if you are concerned about risks. This document is not intended to replace a consultation with your healthcare professional if needed.

4.1. Remaining risks and undesirable effects

- The implant is absorbable. It can lead to inflammation (inflammatory reaction to foreign bodies), bone or cartilage resorption (osteolysis or chondrolysis, rates up to 26% have been reported in the scientific literature) or closed sac (cyst).
- Implant might fail and lead to a new tear (secondary tearing, rates up to 20% have been reported in the scientific literature).
- Other side effects include:
  - Shoulder pain and stiffness (capsulitis, 5 cases (5%) in a clinical study with A'LINK'S®)
  - Pain after surgery (3 cases (3%) in a clinical study with A'LINK'S®)
  - Superficial infection (1 case (1%) in a clinical study with A'LINK'S®)

Any serious incident occurring in relation to the device must be reported without delay to TEKNIMED and the competent local authority where the user and/or the patient is established.

4.2. Warnings and Precautions

No warning and precautions are applicable for patients as this device is intended to be used only by healthcare professionals.

4.3. Summary of any field safety corrective action (FSCA) if applicable

None. No FSCA have been issued since the release of A'Link's® on the market

5. Summary of clinical evaluation and post-market clinical follow-up

5.1. Clinical background

A'Link's® anchor comes from a safe technology. It has been used in surgery for many years. It treats tendon tear in shoulder. Patients have pain alleviation. Patients have improved quality of life. Performance and safety have been shown by clinical studies.

5.2. Clinical evidence for CE marking

A clinical study has been done in 2014 in France. It evaluated performance and safety of A'Link's®. 25 patients were included in the study.
Patients had less pain and better mobility after surgery. The level of activity improved also. Driving was possible again after two months. The return to work was possible after five months.
The advantage of the absorbable anchor was shown (The clinical results of this study confirm that arthroscopic rotator cuff repair can reliably improve both shoulder pain and function, regardless of the tear size.). Bone reconstruction is possible (The advantage of using PLA-TCP composite anchor was demonstrated as the osteoconductive nature of these anchors allows absorption with full bone reconstruction without any side effects or complications. Radiological follow-up confirmed the bone remodelling and reconstruction around the anchor). No issue related to the anchor were reported (No side effects, no complications directly related to the anchor were reported. No dissociation phenomenon, rejection, or consolidation problems were reported).
Another clinical study is on-going. An interim analysis has been done.
102 patients were included in the study. During surgery, no issue related to A'Link's® anchor has been recorded (no adverse events or complications related to A'LINK'S® and its associated instrumentation (tap), and no implant failure were observed). After surgery, pain was much lower (100% of patients at the long-term visit, considered that their health condition had improved after the surgery). No issue related to the anchor were reported.
All data show that A'Link's® anchor is effective and safe.

5.3 Safety

No safety issue, other than those described in section 4.1. and 5.2., were reported.
Above sections (4.1 and 5.2) list all safety issues.
The balance between benefit and risk of using A'Link's is acceptable.

6. Possible diagnostic or therapeutic alternatives

Patients who don't want to be treated with A'Link's® have alternatives. They can reduce their activities. They can use medications. Oral medication, infiltration or physiotherapy are recommended. Drugs may be used to reduce pain (non-steroidal anti-inflammatory drugs (NSAIDs), corticosteroid injections, anabolic androgenic steroids, hyaluronic acid injections, platelet-rich plasma injection, prolotherapy injection, medicinal signalling cells, polydeoxyribonucleotide or glyceryl trinitrate). Therapies without drugs or surgery exist as well (physiotherapy, exercise, extracorporeal shock wave therapy, acupuncture, kinesio taping or microwave diathermy).

When considering alternative treatments, it is recommended to contact your healthcare professional who can take into account your individual situation.

7. Suggested profile and training for users

Product should only be used in clinics or hospitals. It should be used by qualified health care professionals (surgeons). They need to be expert in surgery using bioresorbable anchors.