CONTIPRO

Summary of safety and clinical performance

Fascigel HA®

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

The following information is intended for users/healthcare professionals.

Following this information there is a summary intended for patients.

Issued by: Ing. Jana Poslušná

Signature:

Date: 09/12/2024

Reference number: SSCP-FAS-99

Document revision: 03

1. Device identification and general information

1.1. Device trade name:
Fascigel HA®

1.2. Manufacturer's name and address:
Contipro a.s., Dolní Dobrouč 401, Dolní Dobrouč 56101

1.3. Manufacturer's SRN (single registration number):
CZ-MF-000014702

1.4. Basic UDI-DI
859 51637 9900 NY

1.5. Medical device nomenclature description / text:
P9099 – IMPLANTABLE PROSTHETIC DEVICES - OTHER

1.6. Class of device:
Class III, according to Annex VIII of MDR, rule 8

1.7. Year when the first certificate (CE) was issued covering the device:
N/A

1.8. Authorised representative if applicable; name and the SRN:
N/A

1.9. NB's name (the NB that will validate the SSCP) and the NB's single identification number

Notified Body No. 2265

Address:

3EC International a.s.

Hraničná 18

821 05 Bratislava

Slovakia

2. Intended use of the device

2.1. Intended purpose

Fascigel HA is a sterile medical device designed for the treatment of myofascial chronic back pain. Fascigel provides lubrication, hydration and physiological regeneration of deep fascia, reducing their friction and improving gliding.

2.2. Indication(s) and Intended patient population(s)

Indication: Fascigel HA is indicated to provide a relief from myofascial chronic back pain.

Intended patient population: Adult patients suffering from myofascial chronic back pain.

2.3. Contraindications and/or limitations

Contraindication: Currently, there are no known contraindications for the sodium hyaluronate administration.
The treatment is not suitable for patients undergoing chronic coagulation therapy.
It is not recommended to apply during the treatment of acute inflammation.

Limitation: Do not usen in children and adolescent patients. There are no clinical data on the use of the device during pregnancy or breastfeeding, consult a physician for possible use of the product.

3. Device description

3.1. Description of the device

Fascigel HA is an injectable hyaluronan-based medical device intended to be injected interfascially into the deep fascia/fascia, for the treatment of myofascial chronic back pain. It is a viscoelastic sodium hyaluronate (1%) – 10 mg/ml saline solution. Fascigel HA is clear colourless solution in a sterile package for a single use. Fascigel HA provides lubrication, hydration and physiological regeneration of deep fascia, reducing their friction and improving their gliding.
Sodium hyaluronate is a linear, negatively charged polysaccharide that is a natural compound of the body (mainly as a component of extracellular matrix), therefore, it is a non-toxic substance and does not cause any allergic or adverse reactions. Sodium hyaluronate has unique physical-chemical properties, high moisturizing ability and excellent lubrication properties.

3.2. Mode of action

Hyaluronic acid is a polysaccharide that is naturally in the human body. It is spread out in various tissues e.g. connecting tissue, epithelium and nervous tissue and is one of the crucial components of extracellular matrix. Sodium hyaluronate is important for the proper functioning of the musculoskeletal system, it is a natural part of joints, muscles, tendons and ligaments as well as fascia. Fascia/deep fascia is formed by a multi-layered structure of densely arranged

collagen fibers separated by a thin connective tissue rich in hyaluronan (HA), ensuring a reduction at friction associated with movement (fascia gliding). The reduced ability of individual layers of fascia to slide against each other (and their surrounding structures) causes stiffness and pain in the myofascial structure. Supplementation of thin connective tissue with exogenous hyaluronan offers renewal of the ability of the fascia to smoothly slide over other layers of fascia and over the muscles. Ultrasound-guided injection of Fascigel HA between fascial layers enables to determine the injection site and the injected solution in the interfascial space.
The mechanism of action of the medical device Fascigel HA is therefore the mechanical separation of these layers of fascia. The supplied sodium hyaluronate ensures long-term lubrication of the deep fascia layers. By separating the individual layers and facilitating the sliding movement of the individual fascial layers, back pain and stiffness is alleviated.

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

N/A

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

Fascigel HA is intended to use for injection into deep fascia (in the back area). Use ultrasound transducers to precise guide the injection (with a 20 G – 25 G needle and sufficient length depending on the application site) to the injection site. It is standardly recommended to use one needle to withdraw the product from the vial, and then another to apply Fascigel HA to the patient.

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

N/A

4. Risks and warnings

4.1. Residual risks and undesirable effects

The risk assessment identified risks arising from the application risk analysis and risks associated with the manufacture, packaging, labelling, storage and distribution of the product. The risks identified fall into the categories of low and medium level, with risk control measures identified for medium. There are no significant risks to users of the product or patients that have not been brought to their attention in advance, either in the Information for Use or on the packaging of the product.

Residual risks and adverse events have been communicated in Instruction for use and on packaging of the product.

Contraindications:
Currently, there are no known contraindications for the sodium hyaluronate administration.
The treatment is not suitable for patients undergoing chronic coagulation therapy.
It is not recommended to apply during the treatment of acute inflammation.

Side effects:

Sodium hyaluronate a linear, negatively charged polysaccharide that is a natural compound of the body, therefore, it is a non-toxic substance and does not cause any allergic or adverse reactions. Sodium hyaluronate causes no side effects and is generally well tolerated. Currently there are not known any side effects after administration. Patients may experience mild pain and swelling at the injection site, which will disappear in a short-term interval. Local infection may occur in connection with injection application.

Significant residual risks are identified in the table below including risk probability occurrence and severity of harm. No residual risks nor undesirable effects arising from risk analysis were reported during the performed clinical investigation.

Residual risk and undesirable effects

Residual risk and undesirable effects	Probability of occurrence	Severity of harm	Risk evaluation
Hypersensitivity to hyaluronic acid, allergies related to the application of the device	improbable	minor	acceptable
Significant damage of packaging due to improper handling during transport	unlikely	negligible	acceptable
Application of the product after expiry date	improbable	minor	acceptable
Application of the product with damage primary packaging (loss of sterility)	improbable	critical	acceptable
Application with inappropriate needle	improbable	negligible	acceptable
Application with the same needle for all punctures (blunt needle)	improbable	negligible	acceptable
Single needle application for all punctures (blunt needle)	improbable	negligible	acceptable
Violation of the pleural cavity by mis-targeting during application in the thoracic region	improbable	critical	acceptable
Failure to comply with hygienic conditions during application	improbable	critical	acceptable
Application of too little or too much solution	unlikely	minor	acceptable
Failure to massage the applied solution	unlikely	minor	acceptable
Failure to distribute the applied dose of solution to multiple punctures/locations in the treatment area	occasional	minor	acceptable
Application to a patient on anticoagulation therapy	improbable	serious	acceptable
Application to a patient with acute inflammation	unlikely	minor	acceptable
Application to a patient after physical therapy	unlikely	minor	acceptable
Excessive patient burden shortly after application	unlikely	minor	acceptable

Breakage of vial during disposal (attempt to break apart product parts)	improbable	minor	acceptable
Failure to complete or fill out the implant card correctly	improbable	negligible	acceptable

4.2. Warnings and precautions

The medical device should be used by properly educated health professionals.
Do not use if the product packaging is damaged.
A solution that has not been used immediately after opening needs to be discarded, as its sterility can no longer be ensured.
Expired or used product has to be disposed with ordinary municipal waste. The primary packaging, including any remaining solution, can be disposed of as ordinary municipal waste, other parts of the packaging can be sorted as paper.
Do not use after date of expiry.
Keep out of reach of children.
Do not re-use. Do not re-sterilize.
When used in the thoracic region, ensure careful correct application using probe navigation due to the risk of pneumothorax. Application immediately (within 14 days) after completing physical therapy may lead to unpleasant sensations after application.

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

No field safety correction actions or field safety notices have been issued.

5. The summary of clinical evaluation

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

Assessing various products intended to treat myofascial chronic back pain with different design no equivalent device was found on the market that would give sufficient equivalency for clinical evaluation. Commercially available products differ in construction, composition or way of use.

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

Clinical investigation summary:

Identification of investigation	Multi-centre, open-label, first-in-man study with Fascigel used in adult patients suffered from back pain; ClinicalTrials.gov ID: NCT05625984
Identification of medical device	Fascigel
Intended purpose	The device intended purpose is to help treat back pain by lubricating fascia.
Objectives of the study	To prove safety of the device in terms of a clinical results as well as efficacy.

Study design	Multi-center, open-label, first-in-man prospective study, duration of the study from 26.10.2022 (FSFV) to 13.11.2023 (LSLV)
Primary and secondary endpoint(s)	Primary endpoint - Pain management (VAS scale) Secondary endpoints - Assessment of mobility - Assessmentof pain quality descriptor - Change in HR QOL by SF-36 questionnaire - Subjective evaluation of the treatmnet by investigator/patient - Change in need of analgetics used
Safety critera for evaluation	Each patient will be routinely assessed for any signs of potential adverse events in terms of pain, allergic reactions. There are no expected adverse device effects in the use of this device.
Inclusion/exclusion criteria for subject selection	Inclusion criteria - Back pain (VAS above 4 cm) - Limited range of motion - Duration of pain for over 3 months - Patient willing and able to rpovide the written consent - Ability to communicate welll with th einvestigator in the local language, and to understand an compy with the requirements of the study Exclusion criteria - State adter back surgery - BMI > 35 - Age < 18 years - Pregnant or lactating woman - Patient in terminal stage of living - Patient with known hypersensitivity or allergy to any of substances contained in Medical Device - Patient participating in the intervention clinical study - Alcohol or drug abuse - Patient undergoing chronic coagulation therapy
Number of enrolled subjects	*55*
Study population:	Patients enrolled in the study sufferred from back pain (adult men and women suffering from pain (VAS over 4 cm) for more than 3 months, age limited according to the inclusion criteria)
Summary of study methods	The analysis will include collected and derived continuous and categorical variables. The distribution of study values will be summarized according to the type of study variable involved, for all criteria, with details

	of numbers of subjects and, where relevant, numbers of missing data. Descriptive statistics will be provided for each of the criteria using the following values: ➢ For continuous data: mean, standard deviation of the variable, median, lower/upper quartile, minimum and maximum values. ➢ For qualitative data: absolute counts (N) and percentages (%). All hypotheses will be tested at a 5% level of significance. A descriptive analysis of major protocol violations will be prepared for each subject.
Summary of results	See paragraph down below
Any limitations	No limitation was reported.
Any device deficiency and any device replacements related to safety and/or performance during the study	No device deficiency nor device replacements were reported.

In 2023, first-in-man clinical investigation was conducted to confirm the efficacy and safety of the product. The trial was performed in 3 clinical centres in the Czech Republic, there were enrolled 55 patients totally. Primary efficacy parameter was change of pain (VAS scale) after up to 84 days (12 weeks) after medical device application. The results have shown efficacy as highly statistically significant (week 02: $p=3.02e^{-08}$; week 04: $p=7.00e^{-10}$; week 12: $p=6.70e^{-09}$) of decreasing pain level. Obtained results from secondary endpoints evaluation have shown an improvement of the patient mobility, an improvement of back stiffness and an improvement of pain radiating from the back to the lower limbs. There were 4 Adverse events detected during the course of the study. No SAE was detected. The study is not continuing in the long-term follow up phase.

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

Other clinical data or findings related to Fascigel HA are not yet available in the literature. Immediately after launch, the manufacturer plans to initiate a PMCF study. No changes in the incidence of adverse side effects, events or trends have been reported to date.

5.4. An overall summary of the clinical performance and safety

From results of clinical performance and all safety findings we can consider the use of Fascigel HA as generally safe without major risk to the patient or user. No serious adverse events or undesirable effects were reported during the clinical investigation that could affect the positive benefit-risk ratio of the evaluated Fascigel HA medical device.

Clinical benefits: The product supports hydration, lubrication, physiological regeneration of deep fascia. It improves mobility and relieves stiffness in the back, thereby reducing the degree of pain (decrease of pain level on the VAS scale minimally by at least 2 cm). Results of a clinical study confirmed a reduction of pain in up to 70 % of patients.

The primary target parameter was the change in pain level (VAS) at 84 days after the start of treatment. The mean VAS at initial screening was 70.35 (min 50, max 100). At week 02, the mean value decreased by 20 mm from the VAS scale. At week 04 and week 12, the VAS level decreased by an average of 25 mm and 26 mm, respectively. The results focused on efficacy proved to be highly statistically significant in reducing pain levels. Over the course of the study, the VAS was reduced by 20 mm or more at least one of the visits (week 02, 04 or 12) in 39 of 55 subjects. In 5 subjects, VAS levels were reduced by 60 mm or more at least one of the visits. Thirty-seven of the 55 patients who had long-term pain (more than 999 days) were enrolled in the study.

Evaluation of secondary endpoints yielded statistically significant improvements in patient mobility and health status resulting from evaluation of the SF-36 questionnaire. The other two parameters showed an improvement compared to the patient's baseline condition (assessment of pain descriptors and subjective assessment of treatment by the investigator/patient). The results obtained from the pain characteristic assessment confirmed the improvement in back stiffness, including improvement in pain radiating from the back to the lower limbs. The results of the subjective assessment scores obtained confirmed the highest subjective assessment at week 12, when in 17 cases (30.90% of the treated patients) the treating physician/patient assessed the positive effect with a value of 4 (on a scale of 0-5, with 0 being no change and 5 being the highest improvement). No significant change was observed in the assessment of the last parameter (need for analgesics), hence no increase in analgesic use.

As the ratio of clinical benefits of the product outweighs the residual risks of using the product, the benefit-risk ratio can be considered acceptable.

5.5. Ongoing or planned post-market clinical follow-up (PMCF)

A post-marketing clinical follow-up study is planned after the launch of the product on the market. The initiation of the PMCF study is expected in 2026.

PMCF study plan:

Title	**Multi-centre, open-label PMCF study with Fascigel HA in adult patients suffered from myofascial chronic back pain**
Investigational Product	Fascigel HA
Number of Sites	5–15 sites in the Czech Republic (clinical sites specialized on chronic pain treatment (algesiology) will be selected from private practices, regional hospitals and university hospitals in the Czech Republic)
Intended Purpose	Fascigel HA is a sterile medical device designed for the treatment of myofascial chronic back pain. Fascigel HA provides lubrication, hydration and physiological regeneration of deep fascia, reducing their friction and improving gliding.
Design	Multi-centre, open-label PMCF study.
Primary Objectives	To provide further data on safety of the device in terms of a clinical results as well as efficacy.
Study Duration	The estimated trial duration is 36 months. The recruitment period is about to start approx. Q3 2026.

Sample Size	100–150 patients
Population	Adult patients suffered from myofascial chronic back pain
Inclusion/Exclusion Criteria	Inclusion Criteria Back pain (VAS above 4 cm), Limited range of motion, Duration of pain for over 3 months, Patient willing and able to provide the written consent, Ability to communicate well with investigator in the local language, and to understand and compy with the requirements of the study Exclusion Criteria BMI > 35, Age < 18 years, Pregnant or lactating woman, Patient in terminal stage of living, Patient with known hypersensitivity or allergy to any of substances contained in Medical Device, Patient participating in other interventional clinical study, Alcohol or drug abuse, Patient undergoing chronic coagulation therapy
Studied Product Design	The product is a Class III Medical Device. It´s an injectable hyaluronan-based medical device intended to be injected intrafascially into deep fascia/ fascia, for treatment of chronical back pain. Clear colourless solution of 1% sodium hyaluronate packed in a sterile package for a single use.
Investigational Product Administration	Device is injected directly intrafascially and/or intrerfascially in the concerned place in multiple places laterally. It is inteded for single use.
Control product	No
Efficacy Measurements	Primary Endpoint Pain management (VAS scale) after 6 months (+/- 14 days) Secondary Endpoints Assessment of mobility, Assessment of pain quality descriptors, Change in HR QOL by SF-36 questionnaire Subjective evaluation of the treatment by investigator/patient, Change in need of analgesics use Pain management (VAS scale) after 12 months (+/- 14 days)
Safety Criteria for Evaluation	Each patient will be routinely assessed for any signs of potential adverse events in terms of pain, allergic reactions or infection within the wound. Based on previous clinical experience, there are no expected adverse device effects in the use of this device.
Statistical considerations	The analysis will include collected and derived continuous and categorical variables. Descriptive statistics will be provided for each of the criteria. A descriptive analysis of major protocol violations will be prepared for each subject.

5.6. Statement of conformity

The medical device Fascigel HA meets the requirements of the EU Regulation 2017/745 on medical devices and is in accordance with all general safety and performance requirements and listed in Annex I of this Regulation.

6. Possible diagnostic or therapeutic alternatives

There are many treatments for myofascial pain syndrome, including stretching exercises, ergonomic modifications, pain relievers (e.g. paracetamol, nonsteroidal anti-inflammatory drugs, muscle relaxants), physical modalities, and invasive procedures. Physicians also perform dry needling or inject local anesthetic agents into the trigger points to achieve pain reduction (Tantanatip 2021).

- Tantanatip A, Patisumpitawong W, Lee S. Comparison of the Effects of Physiologic Saline Interfascial and Lidocaine Trigger Point Injections in Treatment of Myofascial Pain Syndrome: A Double-Blind Randomized Controlled Trial. Arch Rehabil Res Clin Transl. 2021 Mar 9;3(2):100119. doi: 10.1016/j.arrct.2021.100119. PMID: 34179755; PMCID: PMC8211995.

7. Suggested profile and training for users

The product should be applied by physicians with appropriate education and training and experience in the application of products using ultrasound probe navigation, in accordance with the enclosed package leaflet.

8. Reference to any harmonized standards and CS applied

a) Applied standards:

EN ISO 10993-1:2020	Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process
EN ISO 10993-3:2014	Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
EN ISO 10993-5:2009	Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-10:2013	Part 10: Tests for skin sensitization
EN ISO 10993-11:2018	Part 11: Tests for systemic toxicity
EN ISO 10993-16:2010	Part 16: Toxicokinetic study design for degradation products and leachables
EN ISO 10993-23:2021	Part 23: Tests for irritation
EN ISO 14155:2020	Clinical investigations of medical devices
EN 556-1:2001	Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices
EN ISO 14971:2019	Medical devices – Application of risk management to medical devices
EN ISO 9001:2015	Quality management systems– Requirements
EN ISO 13485:2016 +A11:2021	Medical devices - Quality management systems– Requirements
ISO 20417:2021	Information supplied by the manufacturer
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

b) Legislative standards for medical devices in the Czech Republic

1. Act. No. 375/2022 Sb., medical devices and in vitro medical devices act

2. Act. No. 90/2016 Sb., conformity assessment of specified products being delivered to the market

3. Act No. 505/1990 Sb., metrology
4. Act No. 477/2001 Sb, packaging
5. Act No. 541/2020 Sb., waste

c) Legislative standards and guidelines for medical devices in EU

1. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April on medical devices
2. Guideline on evaluation of Clinical Data MEDDEV 2.7/1 rev. 4
3. MDCG Guidelines related to the clinical investigation and evaluation

MDCG 2021-28	Substantial modification of clinical investigation under Medical Device Regulation
MDCG 2021-20	Instructions for generating CIV-ID for MDR Clinical Investigations
MDCG 2021-8	Clinical investigation application/notification documents
MDCG 2021-6	Regulation (EU) 2017/745 – Questions & Answers regarding clinical investigation
MDCG 2020-13	Clinical evaluation assessment report template
MDCG 2020-10/1 Rev. 1 MDCG 2020-10/2 Rev. 1	Guidance on safety reporting in clinical investigations Appendix: Clinical investigation summary safety report form
MDCG 2020-8	Guidance on PMCF evaluation report template
MDCG 2020-7	Guidance on PMCF plan template
MDCG 2020-6	Guidance on sufficient clinical evidence for legacy devices Background note N••• on the relationship between MDCG 2020-6 and MEDDEV 2.7/1 rev.4 on clinical evaluation
MDCG 2020-5	Guidance on clinical evaluation – Equivalence
MDCG 2019-9 Rev. 1	Summary of safety and clinical performance
MDCG 2019-8 v2	Guidance document Implant card
MDCG 2021-11	Guidance on Implant Card – Device types

d) Other

1. European Pharmacopeia current version
2. EU Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use - Annex 1: Manufacture of Sterile Medicinal Products

9. Revision history

SSCP revision number	Date issued	Change description	Revision validated by the Notified Body
Rev 01	14/02/2024	Initial version	
Rev 02	30/09/2024	Corrections according to the comments from the notified body	
Rev 03	09/12/2024	Actualization according to the requirements of NB	English version validated by NB

A summary of the safety and clinical performance of the device, intended for patients, is given below

Summary of Safety and Clinical Performance

Document revision: 03

Date issued: 09/12/2024

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:
Fascigel HA®

1.2. Manufacturer; name and address:
Contipro a.s., Dolní Dobrouč 401, Dolní Dobrouč 56101

1.3. Basic UDI-DI:
859 51637 9900 NY

1.4. Year, when the device was first CE-marked:
N/A

2. Intended use of the device

2.1. Intended purpose
Fascigel HA is a sterile medical device designed for the treatment of myofascial chronic back pain. Fascigel provides lubrication, hydration and physiological regeneration of deep fascia, reducing their friction and improving gliding.

2.2. Indication and intended patient group
Indication: Fascigel HA is indicated to provide a relief from myofascial chronic back pain.

Intended patient group: Adult patient suffering from chronic myofascial back pain. There are no available clinical data on the use of the device in children and adolescents, or during pregnancy or breastfeeding.

2.3. Contraindications
Contraindications:
Currently, there are no known contraindications for the sodium hyaluronate administration.
The treatment is not suitable for patients undergoing chronic coagulation therapy.
It is not recommended to apply during the treatment of acute inflammation.

Limitations: There are no available clinical data on the use of the device in children and adolescents, or during pregnancy or breastfeeding.

3. Device description

3.1. Device description and material/substances in contact with patient tissues
Fascigel HA is an injectable hyaluronan-based medical device intended to be injected intrafascially into the deep fascia/fascia, for the treatment of myofascial chronic back pain. It is a viscoelastic sodium hyaluronate (1%) – 10 mg/ml saline solution. Fascigel HA is clear colourless solution in a sterile package for a single use. Fascigel HA provides lubrication, hydration and physiological regeneration of deep fascia, reducing their friction and improving their gliding.

Sodium hyaluronate is a linear, negatively charged polysaccharide that is a natural compound of the body (mainly as a component of extracellular matrix), therefore, it is a non-toxic substance and does not cause any allergic or adverse reactions. Sodium hyaluronate has unique physical-chemical properties, high moisturizing ability and excellent lubrication properties.

3.2. Information about medicinal substances in the device, if any

There are no medicinal substances present in the product.

3.3. Description of how the device is achieving its intended mode of action

Sodium hyaluronate is a polysaccharide that is a natural part of the human body. It is found in various tissues such as connective tissue, epithelium, nervous tissue and is one of the key components of the extracellular space. Sodium hyaluronate is important for the proper function of the musculoskeletal system and is a natural component of joints, muscles, tendons and ligaments as well as fascia.
Fascia/deep fascia is composed of a multi-layered structure of densely arranged collagen fibers separated by a thin connective tissue rich in hyaluronate (HA), providing a reduction in friction associated with sliding movement of the fascia.
The reduced ability of the fascia layers to slide relative to each other (and their surrounding structures) causes stiffness and pain in the myofascial structure.

Replenishing the thin connective tissue with exogenous hyaluronate offers restoration of the ability of the fascia to glide smoothly over other fascia layers and over the muscles. Ultrasound-guided injection of Fascigel HA between the fascial layers allows the injection site to be determined and the solution injected in the interfascial space. Thus, the mechanism of action of the Fascigel medical device is the mechanical separation of these fascia layers. The added sodium hyaluronate provides long-term lubrication of the deep fascia layers. By separating the layers and facilitating the sliding movement of the individual fascial layers, back pain and stiffness is relieved.

3.4. Description of accessories, if any

Fascigel HA is intended for injection into the deep fascia (back area). Use the ultrasound probe to guide the injection (with a 20 G to 25 G needle and sufficient length depending on the injection site) precisely into the injection site. It is standard practice to use one needle to draw the product from the vial and then another to inject Fascigel HA into the patient.

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. How potential risks have been controlled or managed

As part of the risk assessment, the manufacturer has traced and identified all risks that may be associated with the use, application, performance and manufacture, packaging, labelling, storage and distribution of the product. Having evaluated the information obtained, it can be concluded that the benefits arising from the use of Fascigel HA outweigh the potential risks, which are generally considered acceptable. There are no significant risks to users of the

product or to patients that have not been brought to their attention in advance, either in the instructions for use or on the packaging of the product.

Following the placing on the market of the device, the manufacturer will continuously monitor all potential risks associated with the device and evaluate the risks acquired in the post-marketing phase. The risk assessment shall be systematically reviewed to ensure that residual risks and the level of acceptable risk remain at the lowest possible level while maintaining a positive benefit-risk ratio.

4.2. Remaining risks and undesirable effects

The risk assessment identified risks arising from the application risk analysis and risks associated with the manufacturing and other phases of the product. The risks identified fall into the categories of low and medium, with risk control measures identified for medium. There are no significant risks to users of the product or patients that have not been brought to their attention in advance, either in the package leaflet or on the packaging of the product.

Residual risks and adverse reactions are identified in the Instruction for use and on the packaging.
Contraindications: Possible hypersensitivity to sodium hyaluronate is not yet known.
Treatment is not suitable for patients undergoing anticoagulation therapy. It is not recommended for use during treatment of acute inflammation.

Side effects:
Sodium hyaluronate is a linear, negatively charged polysaccharide that is a natural part of the body and therefore is not toxic, nor does it cause allergic or other adverse reactions. Sodium hyaluronate is generally well tolerated. There are currently no known adverse effects following its injection.
Patients may experience mild soreness or swelling at the injection site, but this will subside in a short time (within a few hours/days). Local infection may occur in association with injection.
Consult your physician if any side effects or other unusual reactions occur.

Significant residual risk and undesirable effects are identified in table below including risk occurrence probability and severity of harm. No residual risks or adverse reactions resulting from the risk analysis were reported during the clinical trial.

Residual risk and undesirable effects

Residual risk and undesirable effects	Probability of occurrence	Severity of harm	Risk evaluation
Hypersensitivity to hyaluronic acid, allergies related to the application of the device	improbable	minor	acceptable
Significant damage of packaging due to improper handling during transport	unlikely	negligible	acceptable
Application of the product after expiry date	improbable	minor	acceptable
Application of the product with damage primary packaging (loss of sterility)	improbable	critical	acceptable
Application with inappropriate needle	improbable	negligible	acceptable
Application with the same needle for all punctures (blunt needle)	improbable	negligible	acceptable

Single needle application for all punctures (blunt needle)	improbable	negligible	acceptable
Violation of the pleural cavity by mis-targeting during application in the thoracic region	improbable	critical	acceptable
Failure to comply with hygienic conditions during application	improbable	critical	acceptable
Application of too little or too much solution	unlikely	minor	acceptable
Failure to massage the applied solution	unlikely	minor	acceptable
Failure to distribute the applied dose of solution to multiple punctures/locations in the treatment area	occasional	minor	acceptable
Application to a patient on anticoagulation therapy	improbable	serious	acceptable
Application to a patient with acute inflammation	unlikely	minor	acceptable
Application to a patient after physical therapy	unlikely	minor	acceptable
Excessive patient burden shortly after application	unlikely	minor	acceptable
Breakage of vial during disposal (attempt to break apart product parts)	improbable	minor	acceptable
Failure to complete or fill out the implant card correctly	improbable	negligible	acceptable

4.3. Warnings and precautions

The medical device should be used by properly educated health professionals.
Do not use if the product packaging is damaged. A solution that has not been used immediately after opening needs to be discarded, as its sterility can no longer be ensured. Expired or used product has to be disposed with ordinary municipal waste. The primary packaging, including any remaining solution, can be disposed of as ordinary municipal waste, other parts of the packaging can be sorted as paper. Do not use after date of expiry. Keep out of reach of children. Do not re-use. Do not re-sterilize.
When used in the thoracic region, ensure careful correct application using probe navigation due to the risk of pneumothorax. Application immediately (within 14 days) after completing physical therapy may lead to unpleasant sensations after application.

Observe hygiene rules during the application.
Protect from the sunlight.

4.4. Summary of any field safety corrective action, (FSCA including FSN) if applicable

No field safety correction actions or field safety notices have been issued.

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

5.1. Clinical background of the device

Fascigel HA is an injectable medical device based on sodium hyaluronate for injection into the deep fascia/fascia for the treatment of chronic myofascial back pain.

Similar medical devices containing hyaluronic acid are available on the market for the treatment of pain and limitation of movement in affected tendons and ligaments (technically tendinopathy) or, for example, for the treatment of pain and reduced mobility due to degenerative diseases such as osteoarthritis, joint disease following injury.

Hyaluronic acid has been used for several decades to treat tendon and ligament diseases. Similarly, hyaluronic acid is used in visco-supplementation of joints, where it serves as a replacement for the fluid that lubricates the joint and thus facilitates body movement. Visco-supplementation is a therapeutic method in which a replacement viscoelastic fluid, such as hyaluronic acid, is injected into the joint to replace or enhance the physical and protective functions of synovial fluid, reduce pain and improve joint function. This method is already commonly used in orthopaedics to treat osteoarthritis and is supported by a number of clinical studies.

5.2. The clinical evidence for the CE-marking

A clinical study with Fascigel HA was conducted between 2022 and 2023. A total of 55 patients were included in the study and all 55 patients were eligible for analysis of primary and secondary variables (primary - VAS, secondary - mobility, pain characteristics, SF-36 questionnaire and analgesic use) and for safety analysis.

The primary efficacy parameter was the change in pain level (VAS) at 84 days after treatment initiation. The mean VAS at initial screening was 70.35 (min 50, max 100). At week 02, the mean value decreased by 20 mm from the VAS scale. At week 04 and week 12, the VAS level decreased by an average of 25 mm and 26 mm, respectively. The results focused on efficacy proved to be highly statistically significant in reducing pain levels. Over the course of the study, the VAS was reduced by 20 mm or more at least one of the visits (week 02, 04 or 12) in 39 of 55 subjects. In 5 subjects, VAS levels were reduced by 60 mm or more at least one of the visits. The study enrolled 37 of 55 patients who had long-standing pain (more than 999 days). 34 of 55 patients reported no change in their previous treatment prior to Fascigel HA, and in addition, the Quality-of-Life Questionnaire (SF-36) showed that the level of the "Overall Health" sub score did not change during the study. Therefore, it can be concluded that in the majority of cases, these were indeed patients suffering from chronic pain without a positive response to previous treatment and the described positive effect during the study can indeed be attributed to Fascigel HA.

The mobility (mobility) assessment yielded a statistically significant increase in the Mild Mobility Limitations category and a statistically significant decrease in the Moderate Mobility Limitations category. The results obtained from the pain characteristics assessment confirmed the improvement in back stiffness and also showed an improvement in pain radiating from the back to the lower limbs.

Statistically significant changes were also observed in patients' health status according to the SF-36 questionnaire. The evaluation showed that at week 12 there was a statistically significant change from baseline in the sub scores describing Physical Functioning (p-value 0.002), Role Functioning due to Physical Problems (p-value 0.001), Energy/Fatigue (p-value 0.00006), Social Functioning (p-value 0.0005), Pain (p-value 0.0000002). The improvement in the other subscales

(Role Functioning due to Emotional Problems, Emotional Wellbeing and General Health) was not statistically significant.

The results of the subjective assessment scores confirmed the highest subjective assessment at week 12, where in 17 cases the attending physician/patient rated the positive effect as 4 (on a scale of 0-5, with 0 being no change and 5 being the highest improvement). There was no significant effect on patients' analgesic use during the clinical trial, meaning that there was no increase in consumption.

5.3. Safety

A clinical study has confirmed the safety of Fascigel HA. No serious adverse events were recorded.

Data collected on hyaluronic acid-containing products used in the treatment of joint pain or tendon and ligament disorders in the literature have also demonstrated safety and good tolerability when applied as indicated. No serious or relevant treatment-related adverse effects were observed in the studies analysed.

6. Possible diagnostic or therapeutic alternatives

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

6.1. General description of therapeutic alternatives

Standard treatments for chronic myofascial back pain include stretching exercises, ergonomic adjustments, pain medications (paracetamol, non-steroidal anti-inflammatory drugs, myorelaxants), physical modalities and invasive procedures. Doctors also perform the dry needling method or inject local anaesthetics into trigger points to achieve pain reduction. [1]

1. Tantanatip A, Patisumpitawong W, Lee S. Comparison of the Effects of Physiologic Saline Interfascial and Lidocaine Trigger Point Injections in Treatment of Myofascial Pain Syndrome: A Double-Blind Randomized Controlled Trial. Arch Rehabil Res Clin Transl. 2021 Mar 9;3(2):100119. doi: 10.1016/j.arrct.2021.100119. PMID: 34179755; PMCID: PMC8211995.

7. Suggested training for users

The product is intended for use by physicians with appropriate education, training and knowledge of product application using ultrasound probe navigation. The manufacturer continuously plans and conducts training aimed at users of medical devices.