VISCOSEAL®

SYRINGE Sodium Hyaluronate 0.5%

ACCELERATING POST-ARTHROSCOPY RECOVERY

TRB Your experience Your expertise Your expectations

VISCOSEAL®
SYRINGE

OUR SOLUTION FOR JOINT RECOVERY

Arthroscopy, particularly knee arthroscopy, is a commonly used technique worldwide. Nevertheless, patients may suffer from post-operative complications such as pain, swelling, and impaired mobility of the joint in the short-term due to the lack of synovial fluid in the joint.[1]

Viscoseal has been specially developed to replace the synovial fluid post-arthroscopy and therefore to prevent post-operative complications.

VISCOSEAL® SYRINGE

PRODUCT CHARACTERISTICS

CONCENTRATION CLOSE TO THAT OF HEALTHY SYNOVIAL FLUID

0.5% sodium hyaluronate (50 mg/10 ml)

FREE OF ANIMAL PROTEINS

Sodium hyaluronate obtained by biofermentation

PHYSIOLOGICAL

Isotonic solution with a physiological pH

READY-TO-USE

10 ml pre-filled syringe

SAFE NEEDLE ATTACHMENT

Latex-free syringe equipped with a Luer lock

FACILITATION OF ASEPTIC USE

Sterile in the blister

THE ADVANTAGES OF VISCOSEAL SYRINGE

Temporarily replaces the synovial fluid post-arthroscopy thanks to the lubricating and shock-absorbing properties of sodium hyaluronate[2]

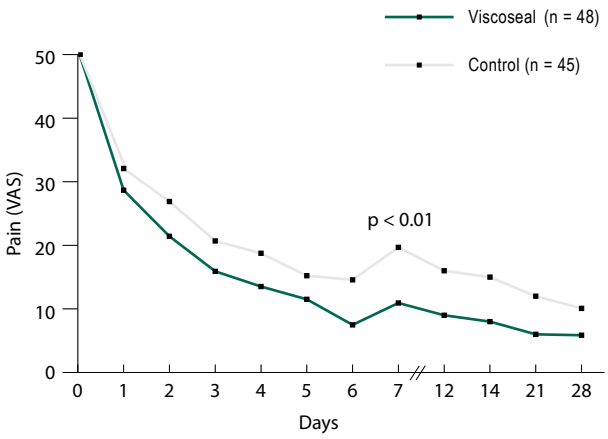
Displaces the irrigating solution left in the joint space, therefore preventing cartilage metabolism impairment[3,4]

Provides an alternative to local anaesthetics and corticosteroids, which have been shown to be chondrotoxic[5-9]

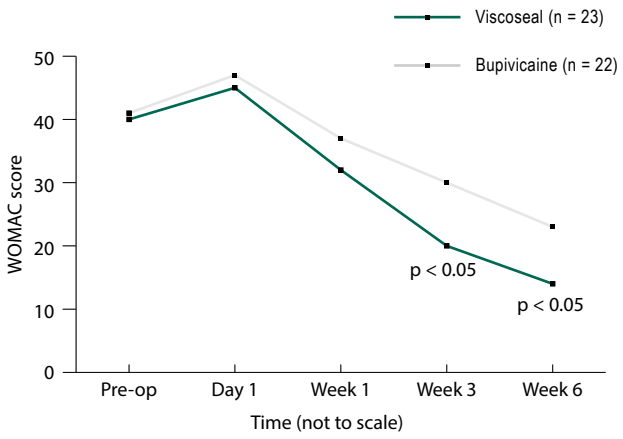
VISCOSEAL®
SYRINGE

PROVEN EFFICACY AND SAFETY FOR PATIENTS

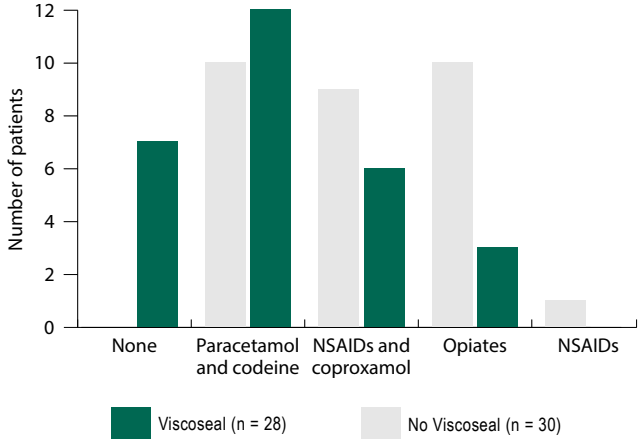
Less pain after surgery[10]



Improved joint function and mobility[11]



Reduced analgesic consumption[15]



After arthroscopy, Viscoseal Syringe:

- Reduces post-operative pain[1,10-16] and effusion[1,11-13,16]
- Improves joint function and mobility[11,16,17]
- Reduces analgesic consumption[11,14,15]
- Reduces the time to discharge from hospital[14,16]
- Has an excellent safety profile[1,10,12-19]

VISCOSEAL® SYRINGE

Instructions for use

VISCOSEAL® SYRINGE – Synovial fluid substitute
Sodium hyaluronate from fermentation 0.5%. Synovial fluid substitute. 10 ml pre-filled syringe in a sterile pack for single use. Sterile by moist heat.

Composition:
1 ml isotonic solution contains 5.0 mg sodium hyaluronate from fermentation, sodium chloride, disodium phosphate, sodium dihydrogen phosphate and water for injections.

Indications:
To relieve pain, improve mobility and promote joint recovery by flushing out irrigating solution and substituting the synovial fluid following arthroscopic procedures or joint lavage of the shoulder or knee joint.

Contra-indications:
Known hypersensitivity to any of the constituents of the product.

Interactions:
Avoid using VISCOSEAL® SYRINGE with materials disinfected with quaternary ammonium salt solutions.

Undesirable effects:
No undesirable effects are expected with VISCOSEAL® SYRINGE when used in the approved indication and at the dosage prescribed. To date, no cases of infections and allergic reactions causally associated with the use of VISCOSEAL® SYRINGE have been reported. However, both risks cannot be completely excluded. The contra-indications must be considered.

Dosage and administration:
The contents and the outer surface of the VISCOSEAL® SYRINGE pre-filled syringe are sterile as long as the sterile pack remains intact. VISCOSEAL® SYRINGE should be used at the end of the arthroscopy after completion of the normal irrigating procedure. Take the pre-filled syringe out of the sterile pack. Remove the cap, attach a suitable needle and secure it by turning slightly. Remove any air bubble, if present, before injection. Introduce VISCOSEAL® SYRINGE into the joint cavity. Alternatively, the pre-filled syringe may be placed directly into a portal in the joint. The introduction of VISCOSEAL® SYRINGE into the joint cavity will help to wash out the remaining irrigation solution.

Precautions:
The general precautions for arthroscopic procedures should be observed. VISCOSEAL® SYRINGE should be instilled accurately into the joint cavity. As no clinical evidence is available on the use of sodium hyaluronate in children, pregnant and lactating women, treatment with VISCOSEAL® SYRINGE is not recommended in these cases. Any solution not used immediately after opening must be discarded. Otherwise the sterility is no longer guaranteed and this may be associated with a risk of infection. Do not use if the pre-filled syringe or the sterile pack are damaged. Store between 2 °C and 25 °C! Do not use after the expiry date indicated on the box. Keep out of the reach of children.

Characteristics and mode of action:
Arthroscopy is a common procedure to visualise, diagnose and treat problems inside a joint. The joint is normally irrigated with solutions such as saline or Ringer lactate before and during arthroscopy in order to allow a clear view of the operation site and to rinse out debris. There is evidence that the presence of these solutions in the joint after irrigation may be detrimental to the cartilage. Furthermore, during the procedure the synovial fluid, which has particular viscoelastic and protective properties due to its hyaluronic acid content, is washed from the joint. Therefore, although the intervention may result in a long-term improvement of joint function, in the short-term patients may suffer from post-arthroscopy complaints like pain, swelling and impaired mobility of the joint. VISCOSEAL® SYRINGE has been developed to relieve these symptoms and promote joint recovery. It contains a highly purified specific fraction of hyaluronic acid produced by fermentation and is devoid of animal protein. Flushing VISCOSEAL® SYRINGE solution through the joint cavity will help remove the remaining irrigating solution and efficiently coat all surfaces of the joint. The VISCOSEAL® SYRINGE solution left in the joint will act as a lubricant and a shock absorber and its macromolecular meshwork will prevent the free passage of inflammatory cells and molecules through the joint cavity.

Presentation:
1 pre-filled syringe of 50 mg/10 ml VISCOSEAL® SYRINGE in a sterile pack for single use.

To be used by a physician only.

Last revision date: 2019-10

The text of this information may vary depending on the country where the product is authorised. In this case, the national authorisation prevails.

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