

VISCOSEAL[®]

SYRINGE Sodium Hyaluronate 0.5%



*Accelerating
post-arthroscopy
recovery*

The first post-arthroscopy synovial fluid replacement

 TRB CHEMEDICA



VISCOSEAL®

is the first post-arthroscopy synovial fluid replacement for restoration of joint homeostasis

Although arthroscopic procedures have been successfully used for many years, post-operative complications are often characterised by pain, effusion and restricted joint mobility. The absence of physiologic synovial fluid within the joint following arthroscopy may exacerbate these problems and prolong the disruption to joint homeostasis.¹

Intra-articular administration of hyaluronic acid (HA) after arthroscopy helps to restore joint homeostasis.²

VISCOSEAL® is designed to relieve pain, improve mobility and promote joint recovery after arthroscopy.

VISCOSEAL® CHARACTERISTICS:

Contains a solution of hyaluronic acid (HA) 0.5%	HA concentration close to the concentration in normal synovial fluid
HA obtained from bacterial fermentation	Highly purified, natural, non-chemically modified product No avian proteins
Isotonic solution, physiological pH	Designed to replace synovial fluid
10 ml pre-filled syringe for single use	Ready-to-use syringe presentation
Syringe equipped with a Luer lock	Safe needle attachment
Terminal sterilisation by moist heat	Sterile syringe in the blister to facilitate aseptic use

VISCOSEAL® is designed to replace synovial fluid post-arthroscopy. The pre-filled presentation offers optimal safety for use in a surgical theatre.

1. Mathies B. Knee Surg Sports Traumatol Arthrosc. 2006;14(1):32-9
2. Waddell DD, Bert JM. Arthroscopy. 2010;26(1):105-11

How to administer VISCOSEAL®

VISCOSEAL® is introduced into the joint cavity at the end of the arthroscopic surgery, immediately after evacuation of the irrigation solution.

- Either inject the VISCOSEAL® syringe with a needle or via a portal incision, or directly connect to the trochar bridge. (Fig. 1)
- Then move the joint through full range of motion to allow VISCOSEAL® to distribute throughout the joint, and coat the synovium and joint surfaces.

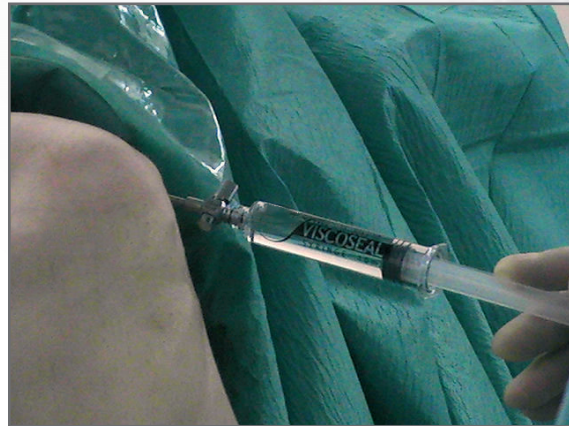


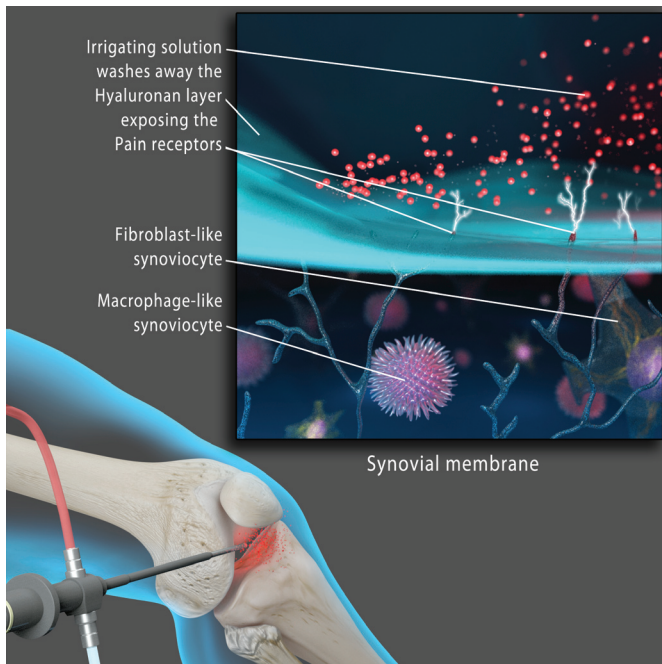
Fig. 1



Negative effects of the irrigation procedure during arthroscopy

During arthroscopy, the use of an irrigating solution washes out the synovial fluid and its major component, HA, from the joint. This leads to :

- Loss of viscoelastic properties, shock absorption and lubrication
- Loss of the protective HA layer coating the cartilage and synovium, leaving these structures open to inflammatory mediators and mechanical damage
- Loss of the masking effect on nociceptors, resulting in increased pain
- Impairment of chondrocyte metabolism due to negative effects of irrigating solution on the cartilage



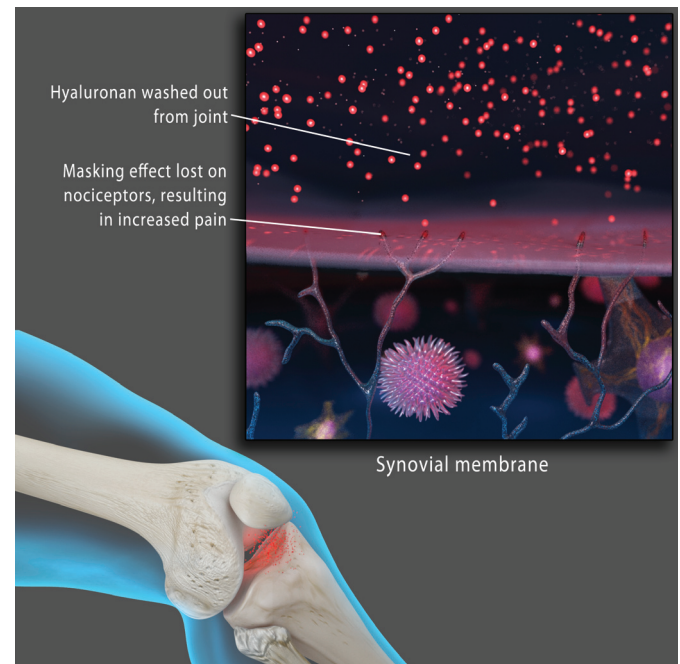
Chondrotoxicity of local anaesthetics and corticosteroids

Post-arthroscopy pain control with intra-articular injections of local anaesthetics and corticosteroids is common practice.

However, several in vitro and in vivo studies have demonstrated the toxicity of lidocaine and bupivacaine to articular chondrocytes resulting in decreased cell viability.⁴⁻⁶

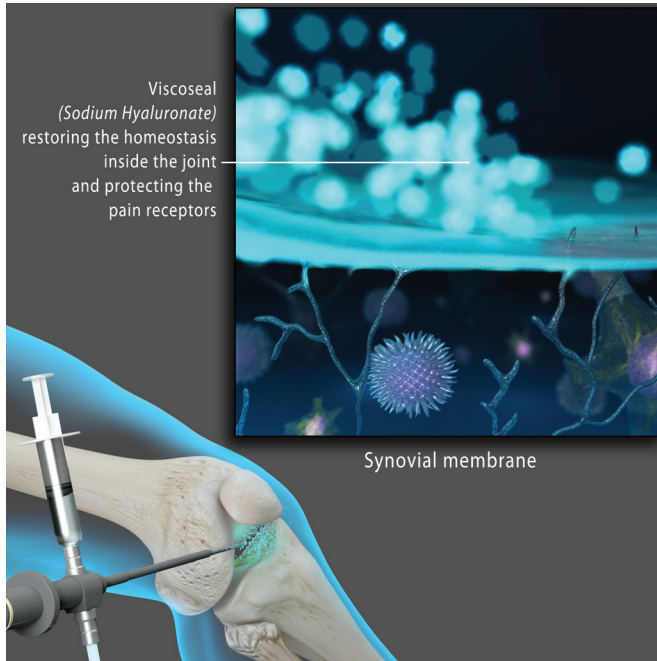
The cytotoxicity seems to be even greater after combined exposure to local anaesthetics and corticosteroids.⁷

The clinical use of intra-articular ropivacaine and bupivacaine should be minimised, as they are considered to be potential chondrotoxic agents.⁸



How does VISCOSEAL® work ?

VISCOSEAL® acts as a temporary replacement for the synovial fluid, restoring physiological functions.



- Displaces any irrigating solution left in the joint space, preventing this solution from impairing cartilage metabolism
- Re-establishes the protective coating over the surface of the cartilage and the synovial membrane, hindering the migration of pro-inflammatory and catabolic mediators and protecting the joint surfaces from mechanical damage
- Replaces the synovial fluid, and therefore the lubricating, shock-absorbing and filtering properties
- Reduces inflammation of the synovium
- Alleviates pain by masking nociceptors

VISCOSEAL® replaces the synovial fluid and displaces the irrigating solution left in the joint

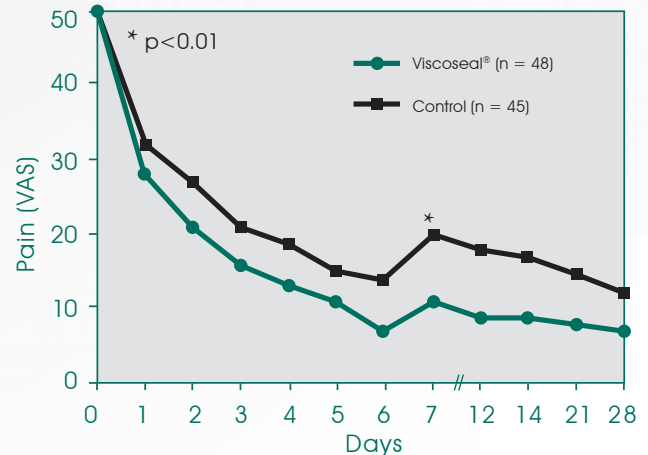
VISCOSEAL®, a physiological alternative to local anaesthetics post-arthroscopy^{10, 11}

3. Bulstra SK et al. J Bone Joint Surg Br.1994;76:468-70
4. Chu CR et al. Arthroscopy. 2006;22(7):693-9
5. Gomoll AH et al. Arthroscopy. 2006;22(8):813-9
6. Lo IKL et al. Arthroscopy. 2009;25(7):707-15
7. Farkas B et al. Clin Orthop Relat Res. 2010;468:3112-20
8. Campo MM et al. Knee Surg Sports Traumatol Arthrosc. 2012;20:239-44

VISCOSEAL® accelerates post-arthroscopy recovery

► Rapid Pain Relief

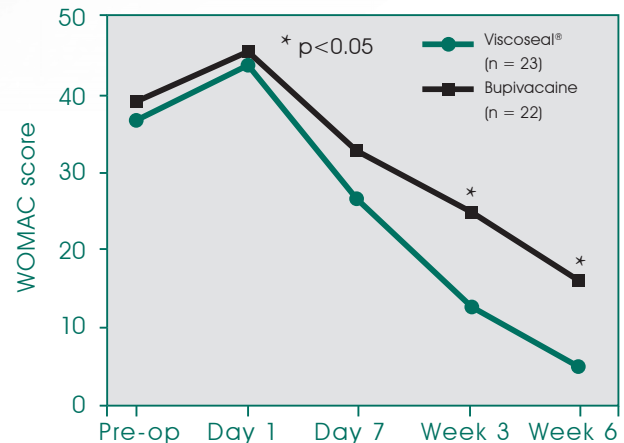
In a clinical study of 93 patients who underwent knee arthroscopy (meniscectomy or joint lavage), those treated with VISCOSEAL® had a significant decrease in pain until the end of the study one month later. The improvement was significant 1 week after surgery compared with standard therapy ($p < 0.01$).⁹



Post-arthroscopy administration of VISCOSEAL® reduced pain in the short-term

► Improvement in Function and Mobility

In a randomized study, 45 patients received 10 ml bupivacaine 0.5% or VISCOSEAL® after knee arthroscopy. Patients who received VISCOSEAL® had a greater improvement in function with a significant decrease in WOMAC score ($p < 0.05$).¹⁰



VISCOSEAL® reduced the mean WOMAC score compared with bupivacaine.

9.Villamor A et al. Osteoarthritis Cartilage. 2004;12(Suppl B):S82

10.Anand S et al. Osteoarthritis Cartilage. 2004;12(Suppl B):S141

► Reduced Analgesic Consumption

Following arthroscopic subacromial decompression, 58 patients who received either VISCOSEAL® plus 10 ml bupivacaine 0.5% or 20 ml bupivacaine alone. At 4 hours post-arthroscopy, 25% of patients who received VISCOSEAL® required no further analgesics.¹¹

Only 11% of patients treated with VISCOSEAL® required opiates compared with 33% of patients in the standard treatment group.¹¹

► Reduced Time to Discharge from Hospital

Patients who received VISCOSEAL® after shoulder arthroscopy were discharged much earlier than those who received bupivacaine alone, (5.2 h vs 9.6 h; $p = 0.0001$).¹¹

► Excellent Safety Profile

The studies conducted with VISCOSEAL® have demonstrated the excellent safety profile of the product. No adverse events due to VISCOSEAL® have been reported.^{1,9-18}

VISCOSEAL® is designed for use after all arthroscopic procedures to decrease pain, improve mobility and promote joint recovery.

11. Funk L, Wykes PR. Osteoarthritis Cartilage. 2004;12 (Supp B): S126

12. Hempfling H. Knee Surg Sports Traumatol Arthrosc. 2007;15(5):537-46

13. Cohen DR et al. J Bone Joint Surg Br. 2007;91-B:118

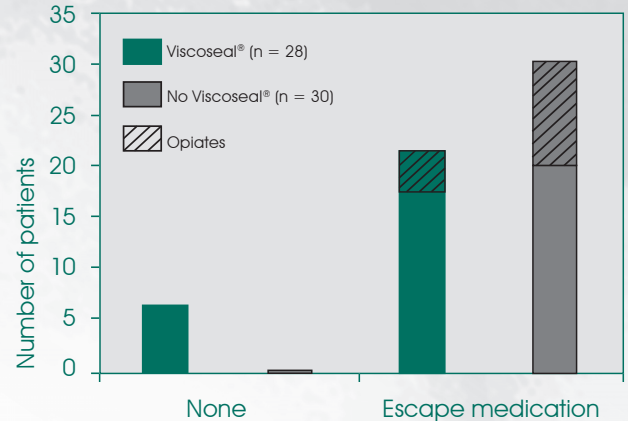
14. Perez-Caballer A et al. J Bone Joint Surg Br. 2007;91-B:141-2

15. Rosa D et al. Tabloid Ortopedia. 2009;4(8):20-1. Italian

16. Thein R et al. Orthopedics. 2010;33(10):724

17. Chau JY et al. Paper presented at: 30th Annual Congress of the Hong Kong Orthopaedic Association (HKOA), 2010 Nov 27-28; Hong Kong

18. Yip GW et al. Paper presented at: 30th Annual Congress of the Hong Kong Orthopaedic Association (HKOA), 2010 Nov 27-28; Hong Kong



After arthroscopic subacromial decompression, patients who received VISCOSEAL® required less analgesia.

Bupivacaine



VISCOSEAL®





INSTRUCTIONS FOR USE

VISCOSSEAL® SYRINGE

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.

Intended use:

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.

Contra-indications:

Known hypersensitivity to any of the constituents of the product.

Interactions:

No information on the incompatibility of VISCOSSEAL® with other solutions for intra-articular use is available to date.

Side effects:

No undesirable effects are expected with VISCOSSEAL® when used in the approved indication and at the dosage prescribed. The contra-indications must be considered.

Directions for use:

The contents and the outer surface of the VISCOSSEAL® pre-filled syringe are sterile as long as the sterile pack remains unbroken. VISCOSSEAL® 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. Alternatively, the pre-filled syringe may be placed directly into a portal in the joint. Remove any air bubble, if present, before introduction. Introduce VISCOSSEAL® into the joint cavity. The introduction of VISCOSSEAL® into the joint cavity will help to displace any remaining irrigation solution.

Precautions:

The general precautions for arthroscopic procedures should be observed. VISCOSSEAL® should be instilled accurately into the joint cavity. As VISCOSSEAL® does not contain preservatives, any solution not used immediately after opening should be discarded. 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. VISCOSSEAL® 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. Instilling VISCOSSEAL® into the joint cavity will help displace any remaining irrigating solution and efficiently coat all surfaces of the joint. VISCOSSEAL® 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. In addition, hyaluronic acid is able to promote wound healing.

Presentation:

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

To be used by a physician only.

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