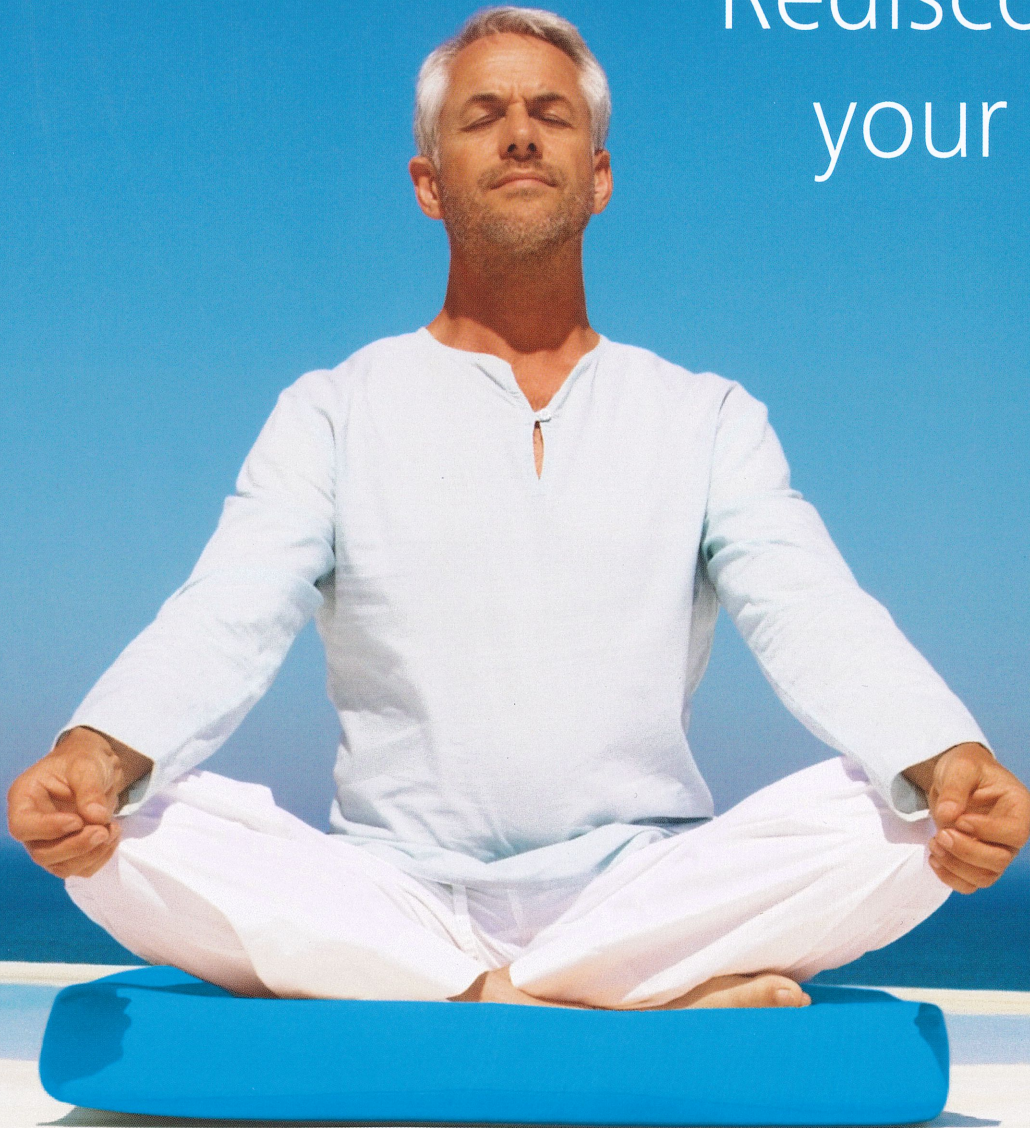


AFTER ARTHROSCOPY:  
Rediscover  
your mobility!



 **VISCOSEAL<sup>®</sup>**  
SYRINGE

The first post-arthroscopy synovial fluid replacement.

Product information

**J.B. Implants Services bv**

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 **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 restriction of joint mobility which could also be caused by the lack of synovial fluid and absence of joint homeostasis.<sup>1</sup>

**Intra-articular administration of hyaluronic acid (HA) after arthroscopy helps to restore joint homeostasis.<sup>2</sup> VISCOSEAL® is intended to relieve pain, improve mobility and promote joint recovery after arthroscopy.**

## VISCOSEAL® SYRINGE characteristics:

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

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

## How to administer VISCOSEAL®?

**VISCOSEAL® is introduced into the joint cavity at the end of the arthroscopic surgery, immediately after completion of the irrigation procedure.**

- Attach a suitable needle (for example 18 G) to the Luer lock and inject into the joint cavity through a portal already placed in the joint.
- Alternatively, introduce the Luer lock to the portal already placed in the joint and inject VISCOSEAL® into the joint cavity.
- Move the joint through full range of motion to allow VISCOSEAL® to distribute throughout the joint, and coat synovium and joint surfaces.

**If a drain is placed in the operated joint, introduce VISCOSEAL®, clamp the drain and manipulate the joint for several minutes in order to allow the product to coat the synovium and cartilage surfaces.**

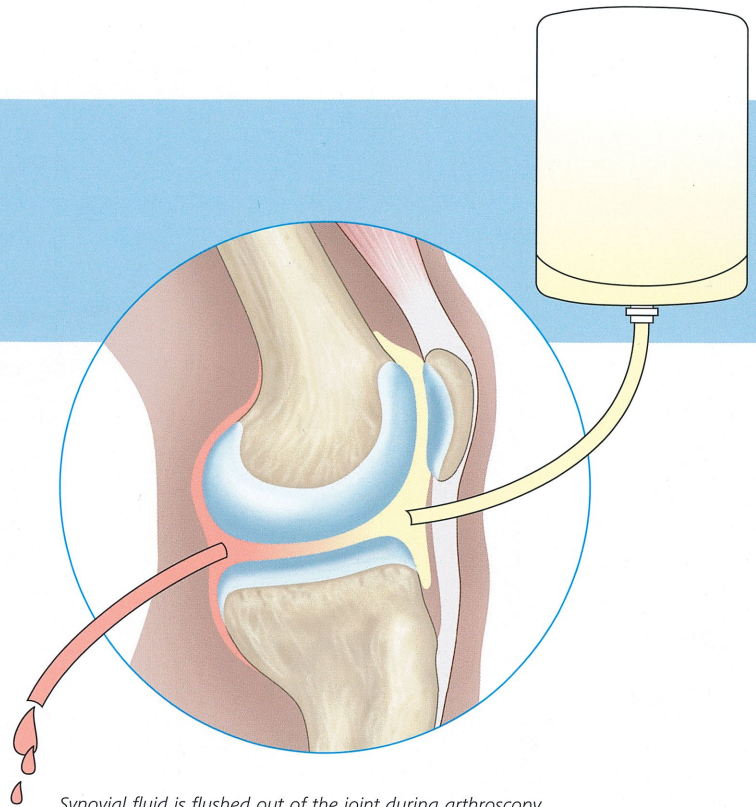


# Negative effects of the irrigation procedure during arthroscopy

During arthroscopy, the use of 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<sup>3</sup>



*Synovial fluid is flushed out of the joint during arthroscopy.*

## Chondrotoxicity of local anaesthetics and corticosteroids

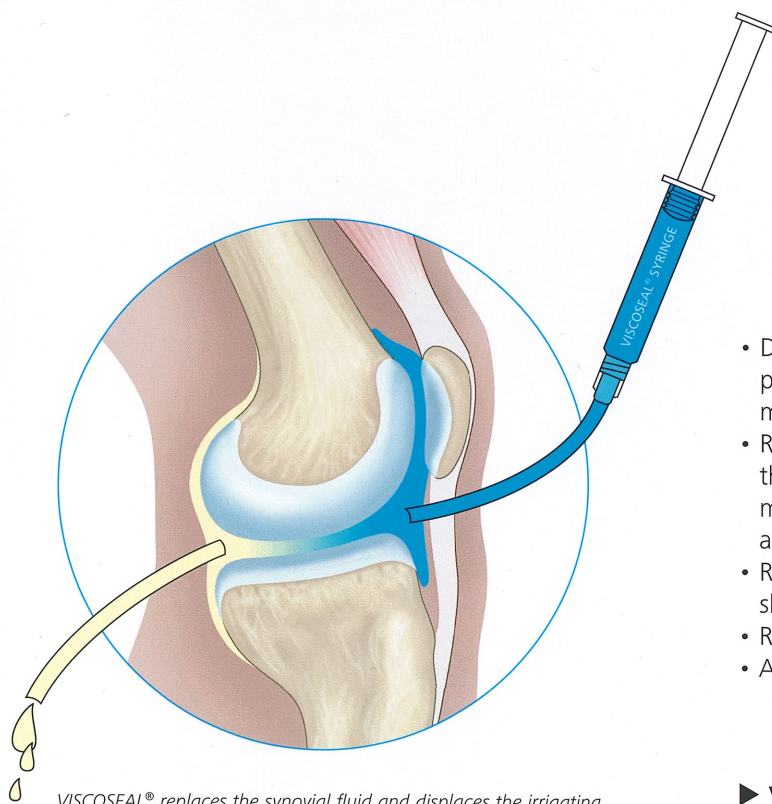
Post-arthroscopy pain control with intra-articular injections of local anaesthetics and corticosteroids is common practice. However, several *in vitro* and *in vivo* studies have demonstrated the toxicity of lidocaine and bupivacaine to articular chondrocytes resulting in a decreased cell viability.<sup>4-6</sup>

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

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

# How does VISCOSEAL<sup>®</sup> work?

**VISCOSEAL<sup>®</sup> acts as a temporary replacement for the synovial fluid, restoring normal physiological functions.**



VISCOSEAL<sup>®</sup> replaces the synovial fluid and displaces the irrigating solution left in the joint.

- 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<sup>®</sup>, the alternative therapy to local anaesthetics post-arthroscopy<sup>10-11</sup>**

<sup>1</sup> Mathies B. *Knee Surg Sports Traumatol Arthrosc.* 2006; 14 (1): 32-9

<sup>2</sup> Waddell DD, Bert JM. *Arthroscopy.* 2010; 26 (1): 105-11

<sup>3</sup> Bulstra SK et al. *J Bone Joint Surg Br.* 1994; 76: 468-70

<sup>4</sup> Chu CR et al. *Arthroscopy.* 2006; 22 (7): 693-9

<sup>5</sup> Gomoll AH et al. *Arthroscopy.* 2006; 22 (8): 813-9

<sup>6</sup> Lo IKL et al. *Arthroscopy.* 2009; 25 (7): 707-15

<sup>7</sup> Farkas B et al. *Clin Orthop Relat Res.* 2010; 468: 3112-20

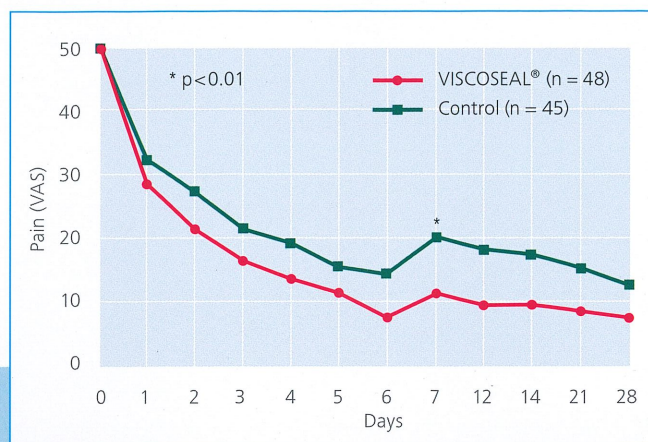
<sup>8</sup> Campo MM et al. *Knee Surg Sports Traumatol Arthrosc.* 2012; 20: 239-44



# VISCOSEAL<sup>®</sup> 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<sup>®</sup> had a significant decrease in pain until the end of the study one month later. The improvement was significant 1 week after surgery compared to standard therapy ( $p < 0.01$ ).<sup>9</sup>

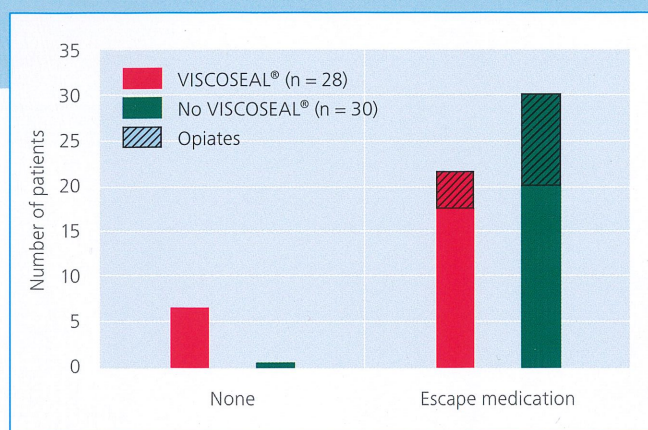


Post-arthroscopy administration of VISCOSEAL<sup>®</sup> reduced pain in the short-term.

## Reduced Analgesic Consumption

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

Only 11% of patients treated with VISCOSEAL<sup>®</sup> required opiates compared with 33% of patients in the standard treatment group.<sup>10</sup>



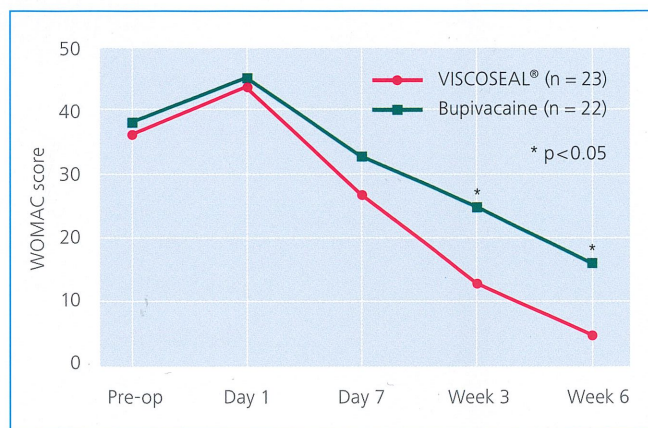
After arthroscopic subacromial decompression, patients who received VISCOSEAL<sup>®</sup> required less analgesia.

## Reduced Time to Discharge from Hospital

Patients who received VISCOSEAL<sup>®</sup> after shoulder arthroscopy were discharged much earlier than those who received bupivacaine alone, (5.2 h vs 9.6 h;  $p = 0.0001$ ).<sup>10</sup>

## Improvement in Function and Mobility

In a randomized study, 45 patients received 10 ml bupivacaine 0.5% or VISCOSEAL<sup>®</sup> after knee arthroscopy. Patients who received VISCOSEAL<sup>®</sup> had a greater improvement in function with a significant decrease in WOMAC score ( $p < 0.05$ ).<sup>11</sup>



VISCOSEAL<sup>®</sup> reduced the mean WOMAC score compared to bupivacaine.

## Excellent Safety Profile

The studies conducted with VISCOSEAL<sup>®</sup> have demonstrated the excellent safety profile of the product. No adverse events due to VISCOSEAL<sup>®</sup> have been reported.<sup>1, 9-18</sup>

**VISCOSEAL<sup>®</sup> is indicated immediately after all arthroscopic procedures to decrease pain, improve mobility and promote joint recovery.**

<sup>9</sup> Villamor A et al. *Osteoarthritis Cartilage*. 2004; 12 (Suppl B): S 82

<sup>10</sup> Funk L, Wykes PR. *Osteoarthritis Cartilage*. 2004; 12 (Suppl B): S 126

<sup>11</sup> Anand S et al. *Osteoarthritis Cartilage*. 2004; 12 (Suppl B): S 141

<sup>12</sup> Hempfling H. *Knee Surg Sports Traumatol Arthrosc*. 2007; 15 (5): 537-46

<sup>13</sup> Cohen DR et al. *J Bone Joint Surg Br*. 2007; 91-B: 118

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

<sup>15</sup> Rosa D et al. *Tabloid Ortopedia*. 2009; 4 (8): 20-1. Italian

<sup>16</sup> Thein R et al. *Orthopedics*. 2010; 33 (10): 724

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

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





## INSTRUCTIONS FOR USE

### Synovial fluid substitute

#### 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.

#### 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.

#### Contra-indications:

Known hypersensitivity to any of the constituents of the product.

#### Interactions:

Avoid using VISCOSSEAL® SYRINGE with materials disinfected with quaternary ammonium salt solutions.

#### Undesirable effects:

Es sind keine unerwünschten Wirkungen zu erwarten, wenn VISCOSSEAL® No undesirable effects are expected with VISCOSSEAL® 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 VISCOSSEAL® 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 VISCOSSEAL® SYRINGE pre-filled syringe are sterile as long as the sterile pack remains intact. VISCOSSEAL® 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 VISCOSSEAL® SYRINGE into the joint cavity. Alternatively, the pre-filled syringe may be placed directly into a portal in the joint. The introduction of VISCOSSEAL® SYRINGE into the joint cavity will help to wash out the remaining irrigation solution.

#### Precautions:

The general precautions for arthroscopic procedures should be observed. VISCOSSEAL® 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 VISCOSSEAL® 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.

VISCOSSEAL® 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 VISCOSSEAL® SYRINGE solution through the joint cavity will help remove the remaining irrigating solution and efficiently coat all surfaces of the joint. The VISCOSSEAL® 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. In addition, hyaluronic acid is able to promote wound healing.

#### Presentation:

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

#### To be used by a physician only.

Last revision date: 2017-02