Chitogel Endoscopic Sinus Surgery Kit

INSTRUCTIONS FOR USE | CSK–4 | ENGLISH

Chitogel™

Contents

One Chitogel Endoscopic Sinus Surgery Kit contains:

- Sealed vial **A** containing 12 mL Sodium Phosphate buffer solution
- Sealed vial **B** containing 350 mg Dextran Aldehyde powder
- Sealed vial **C** containing 12 mL Chitosan Succinamide solution
- Fluid dispensing connector
- Two (2) mixing cannulae
- Malleable cannula
- Two (2) sterile 20 mL Luer Lock syringes

PREPARATION TIME — 20 MINUTES

CONTAINS CHITOSAN (SHELLFISH)

AND

DEXTRAN *(Microbial Origin — Produced by fermentation using Leuconostoc mesenteroides)*

DISPOSAL
Dispose of the Chitogel Endoscopic Sinus Surgery Kit per institutional guidelines.

CAUTION
Federal (USA) law restricts this device to sale by or on order of a physician.

ADVERSE EVENTS
Should be reported to the manufacturer or local regulatory authority.

Warnings

- Chitogel Endoscopic Sinus Surgery Kit contains chitosan from shellfish and should not be used in patients with known allergic responses to shellfish. Physicians should test for shellfish allergic response if status unknown, prior to use.
- The Chitogel Endoscopic Sinus Surgery Kit should not be used in surgery involving any of the following complications:
  – Any form of cerebrospinal fluid leak; or
  – Any form of ophthalmic complication, including but not limited to orbital hemorrhage or hematoma and exposure of the orbital tissues.
- In rare instances, the physiochemical condition associated with Functional Endoscopic Sinus Surgery (FESS), both with and without material application, may present a risk of toxic shock syndrome (TSS). Warning signs of TSS include: sudden fever (usually 39°C or more), vomiting, diarrhea, dizziness, fainting (or near fainting when standing up), and/or a rash that looks like a sunburn.
- Foreign body reaction may occur as with most surgical adjuvant treatments.
- Chitogel Endoscopic Sinus Surgery Kit must be used according to the instructions for use. Read instructions prior to use.

Precautions

- Verify that the surgical field is not bleeding excessively. Control excessive bleeding, as you would normally, prior to application of the Chitogel Endoscopic Sinus Surgery Kit material.
- Inspect the packaging to be sure that it is intact and undamaged prior to use. Do not use the product if the packaging is opened or damaged.
- Do not reuse or resterilize Chitogel Endoscopic Sinus Surgery Kit.
- Inspect the kit contents prior to use. Do not use the product if any of the sealed vials appear to have been opened or to have leaked, or if any of the components of the kit appear to be damaged.
- Use product judiciously over areas of surgical injury. Over-application can lead to unintended gel migration or aspiration.

Indications for use

The Chitogel Endoscopic Sinus Surgery Kit is indicated for use in patients undergoing nasal /sinus surgery as a space occupying packing to:

- Separate tissue or structures compromised by surgical trauma;
- Separate and prevent adhesions between mucosal surfaces in the nasal cavity and minimize ostial stenosis following endoscopic sinus surgery;
- Control minimal bleeding following surgery or trauma by tamponade effect, blood absorption and platelet aggregation;
- Act as an adjunct to aid in the natural healing process.

The Chitogel Endoscopic Sinus Surgery Kit is indicated for use as a nasal packing to treat epistaxis.

Contraindications

Patients with known shellfish allergies.

Symbol identification

STERILE EO	Sterilized using ethylene oxide
STERILE	Sterilized using steam
STERILE R	Sterilized using irradiation
Rx ONLY	Federal (USA) Law restricts this device to sale by or on order of a physcian
	Do not use if package is damaged
	Caution
	Consult instructions for use
	Single use / Do not re-use

REF	Reference number
LOT	Lot number
	Date of manufacture
EC REP	Authorized representative in the European Community CE 0297
	Use by
	Manufacturer
	Store under dry conditions
	Store at or below 25°C

General instructions

The Chitogel Endoscopic Sinus Surgery Kit (the “Kit”) contains components and equipment for the preparation of a nasal gel (the “Gel”) to be applied to the sinus cavities via a supplied and specifically designed malleable cannula.

The Gel preparation will take approximately 20 minutes, so preparation must start sufficiently in advance of when the Gel is expected to be used in surgery.

Once the Gel has been prepared it should be applied to the sinus cavities on both sides within one hour using the malleable cannula supplied with the Kit.

The Gel must be prepared on a sterile surface following these instructions.

There are two main components to the Gel.

1. Dextran Aldehyde (**B**), which is a dry powder, and is reconstituted into a liquid form through mixing the powder with a liquid Sodium Phosphate Buffer (**A**). Both of these components are supplied sterile.
2. The second component Chitosan Succinamide (**C**), is a liquid and is also supplied sterile. The components of the Gel need to be combined following the detailed **Gel Combination Instructions** on the other side of this instruction pamphlet.

Post-Operative Instructions

The patient should be advised to undertake normal saline nasal washes for two weeks following surgery.

The patient should be advised that the nasal washing should be conducted using a normal nasal saline washing solution and each wash should use approximately 8 ounces / 240 mL.

The patient must have a post operative review by the surgeon, within 1–2 weeks of the surgery.

At the first post-operative review by the surgeon, any remaining Gel in the sinus cavity should be removed, ideally with suction.

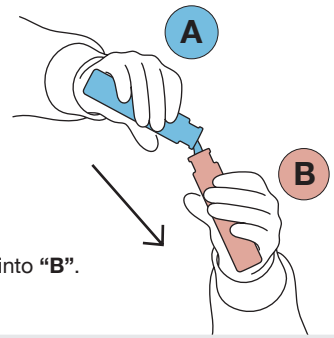
Chitogel Endoscopic Sinus Surgery Kit / Gel Combination Instructions

Scan to watch our Chitogel Mixing Video

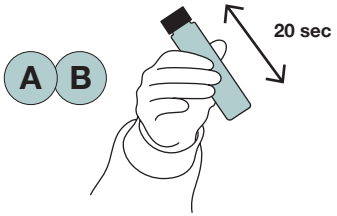
If you are unsure on the mixing process below or experience issues with gel consistency, please contact the Chitogel team.

Chitogel™

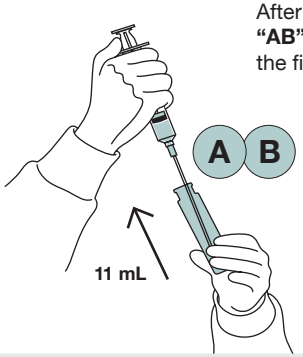
Step One: Preparation



Pour **"A"** into **"B"**.



Re-cap **"B"** and shake the new **"AB"** solution **vigorously** for 20 seconds.

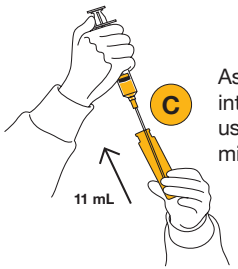


After shaking, aspirate 11 mL of **"AB"** into the first syringe using the first mixing cannula.

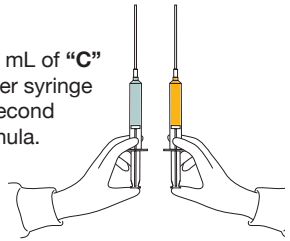
15 min

After aspirating, allow at least 15 minutes for **"AB"** to set.

Step Two: Mix Gel

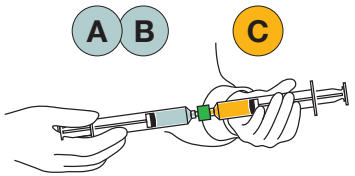


Aspirate 11 mL of **"C"** into the other syringe using the second mixing cannula.



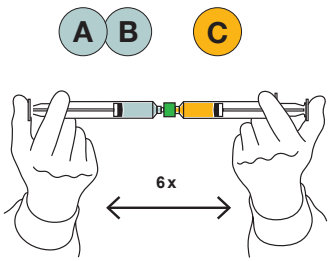
Ensure the volumes of **"AB"** and **"C"** are equal. Eject any excess.

Then, remove the mixing cannulae from both syringes and attach the syringes together using the green fluid dispensing connector.



Set syringes aside on your instrument trolley until you receive warning from your surgeon to mix **(approximately 5 minutes before gel application).**

Once you have received confirmation from your surgeon, mix **"AB"** with **"C"** back and forth 6 times.



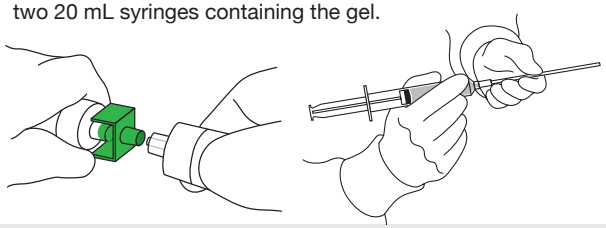
5 min

Then, wait at least 5 minutes for **"AB"** and **"C"** to form the gel.

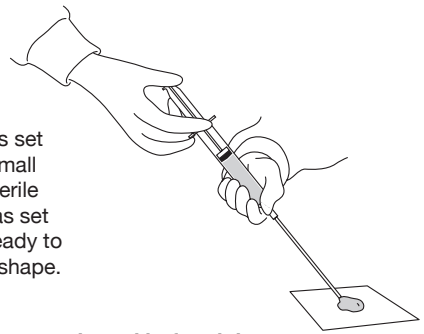
Step Three: Apply

Split the gel evenly between the two 20 mL syringes and disconnect both syringes from the connector.

Then, attach the malleable cannula to one of the two 20 mL syringes containing the gel.



Check the gel has set by squeezing a small amount onto a sterile drape. The gel has set properly and is ready to use if it holds its shape.

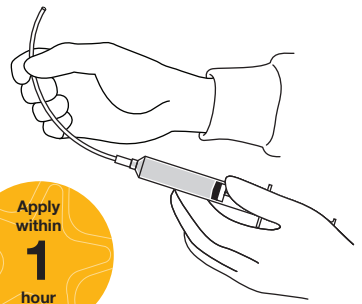


⚠ **Caution: do not use the gel before it has set.**

Once gel has reached the right consistency, it is ready to apply to the sinuses.

For optimal results, apply the gel within **1 hour.**

Apply within 1 hour



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