Chitogel™

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Chitogel Endoscopic Sinus Surgery Kit

INSTRUCTIONS FOR USE
CSK–4

ENGLISH

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.

VERSION 4.00

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	
	Use by	
	Manufacturer	
EC REP	Authorized representative in the European Community	CE 0297
	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. Chitosan Succinamide (**C**), is a sterile liquid. 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.

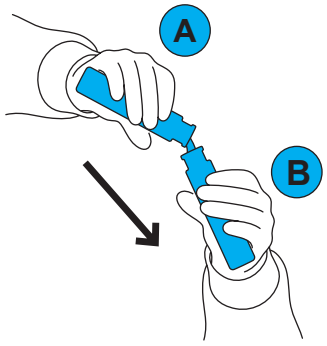
At the first post-operative review by the surgeon, any remaining Gel in the sinus cavity should be removed, ideally with suction.

Chitogel Endoscopic Sinus Surgery Kit / Gel Combination Instructions

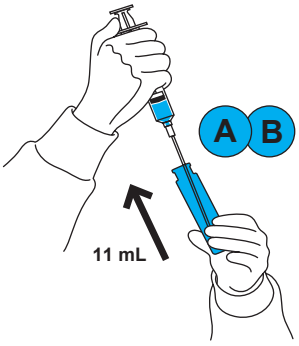
Chitogel™

STEP ONE: PREPARATION

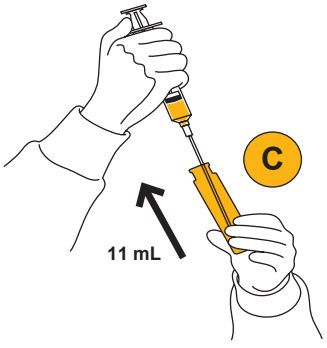
Pour "**A**" into "**B**". Then re-cap "**B**" and shake for 20 seconds



Aspirate **11 mL** of the new liquid "**AB**" into the first 20 mL syringe using the first mixing cannula.



Aspirate **11 mL** of "**C**" into the the second 20 mL syringe using the second mixing cannula.

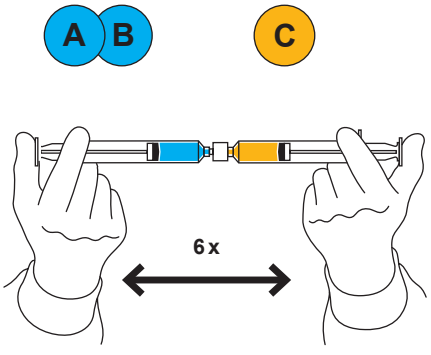


Wait at least 15 minutes to allow **AB** to fully combine before mixing "**AB**" & "**C**"

STEP TWO: MIX GEL

Remove the mixing cannulas. Then attach the syringe containing "**C**" to the syringe containing "**AB**" via the fluid dispensing connector.

Mix "**AB**" with "**C**". Repeat at least 6 times.



Wait at least 5 minutes to allow "**AB**" and "**C**" to set into the Gel

STEP THREE: APPLY

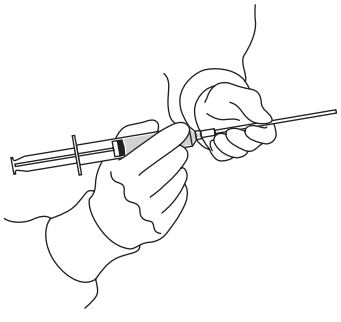
Split the Gel evenly between the two 20 mL syringes.

Then disconnect the syringes from the fluid dispensing connector.

Check the Gel has set by inverting one of the syringes containing the Gel and aspirating an air bubble into the syringe. If the Gel has set, the air bubble will not move in the syringe.

Caution: do not use the Gel before it has set.

Attach the malleable cannula to one of the two 20 mL syringes containing the Gel



Apply the Gel to the sinus cavity by bending the tip of the malleable cannula for the angle required to place into the sinus.

Leave space in the floor of the nose for bilateral nasal airway. Remove with suction any Gel which has fallen to the floor of the nose during application.

Repeat for the second side.

The Gel should be applied within one hour of mixing.