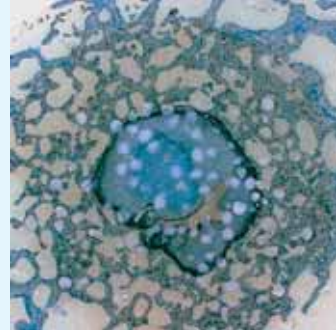


# chronOS Inject. Synthetic Bone Substitute – Injectable, Osteoconductive, Resorbable.

## Technique Guide



**The answer to  
bone voids**



# Table of contents

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<b>Introduction</b>	<b>2</b>
<b>Case Study</b>	<b>3</b>
<b>Indications and Contraindications</b>	<b>4</b>
<b>Mixing System</b>	<b>5</b>
<b>Surgical Technique</b>	<b>7</b>
<b>Cleaning and Care</b>	<b>17</b>
<b>Bibliography</b>	<b>19</b>

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 Image intensifier control

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## **Warning**

This description is not sufficient for immediate application of the instrumentation. Instruction by a surgeon experienced in handling this instrumentation is highly recommended.

# Introduction

## Introduction

chronOS Inject is a synthetic calcium phosphate bone substitute. The material is injectable, osteoconductive, and resorbable. Irregular bone defects can be completely filled with chronOS Inject using a minimally invasive technique. chronOS Inject hardens without exothermal reaction. The hardening process also proceeds in a humid environment.

### chronOS Inject is osteoconductive

The implant is biphasic in its hardened state and consists of a brushite matrix and  $\beta$ -tricalcium phosphate ( $\beta$ -TCP) granules (Fig. 1). Brushite is a resorbable calcium phosphate (dicalcium phosphate dihydrate). The brushite matrix resolves in the interface between the implant and bone (osteoid), thus permitting the ingrowth of new bone. This process is called osteoconduction. The spherical  $\beta$ -TCP granules resorb more slowly than the brushite matrix and act as an anchor for new bone (Figs. 2 and 3).

### chronOS Inject is resorbed and transforms into bone

In the first phase of resorption, the brushite matrix resolves in the area of the osteoid, and in the second phase, the  $\beta$ -TCP granules are completely transformed into bone matrix within 6 to 18 months. In vivo, about 80% of chronOS Inject is transformed to bone within 6 months. Resorption takes place radially from the periphery to the centre.

### chronOS Inject is synthetic

All components of chronOS Inject are completely synthetic. The manufacturing process guarantees a controlled, consistent, and reproducible implant quality.

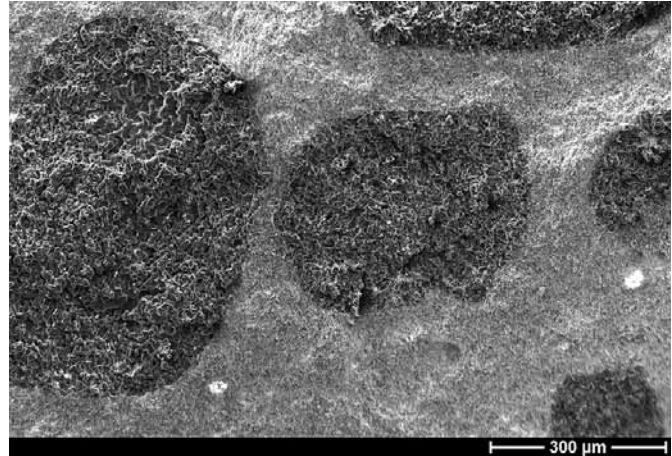


Fig. 1: REM micrograph of hardened chronOS Inject. The  $\beta$ -TCP granules are visible as dark, circular areas within the (lighter) brushite matrix.

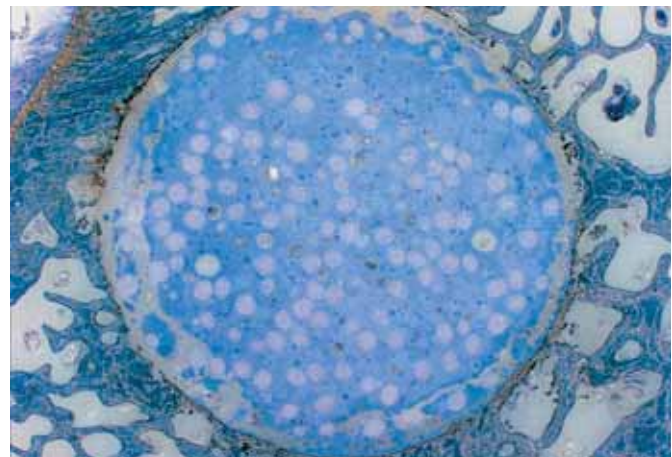


Fig. 2: Histology of a bone defect filled with chronOS Inject 2 weeks postoperative (drill hole  $\varnothing$  8 mm, distal femur of an adult sheep). The  $\beta$ -TCP granules are visible as pale blue areas within the (darker) matrix.

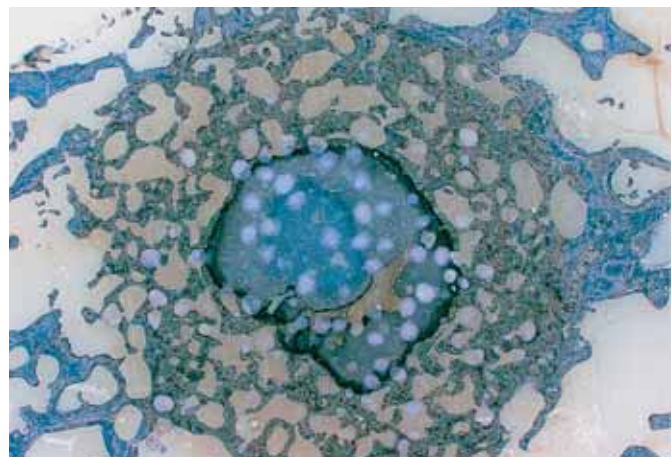


Fig. 3: Histology of a bone defect filled with chronOS Inject 24 weeks postoperative (drill hole  $\varnothing$  8 mm, distal femur of an adult sheep). New bone formation occurs from the periphery toward the centre.

# Case Study

## X-rays of a tibial head impression fracture 41-B3

The fracture is reduced and fixed by two AO screws. The defect is filled with chronOS Inject. Female patient, 64 years old (source: Dr. C. Ryf, Davos Hospital, Switzerland).



Preoperative, lateral view



Preoperative, AP view



Postoperative, AP view



6 months postoperative, AP view

# Indications and Contraindications

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## Indications

chronOS Inject fills bone defects of traumatic and iatrogenic origin and defects resulting from reconstruction. Use is indicated in:

### Trauma

Treatment primarily of metaphyseal bone defects, e.g., in the radius, tibia, calcaneus, humerus, femur, and metacarpals

### Corrections

Filling of bone or resection defects after osteotomy or bone harvesting, e.g., in the proximal tibia, distal femur, the iliac crest, and generally for arthrodeses.

### Reconstruction

Filling of bone voids after the removal of cysts and benign tumours, filling of post-traumatic bone defects.

**Warning:** Fractures must be appropriately reduced prior to applying chronOS Inject. In view of the limited mechanical properties of chronOS Inject, it is advisable to provide adequate stabilization by means of internal fixation, especially in load-bearing indications.

## Contraindications

chronOS Inject may not be used in the following indications:

- Acute and chronic infections at the operation site (bone or soft tissue infections)
- Untreated malignant lymphoma or myeloma
- Defects in the region of an open epiphysis
- Open fractures
- Fractures with open access to the joint after reduction
- Filling of osteochondral defects
- Pathological calcium metabolism (e.g., endocrinopathies)
- Impaired renal function
- Vertebroplasty
- Filling of cranial defects
- Onlay augmentations in the maxillofacial area

# Mixing System

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## Mixing system

The components of chronOS Inject are sterile packed.

chronOS Inject is available in three sizes: 2.5 cc, 5 cc, and 10 cc.

### Supplied as:

Powder component in application cartridge



Liquid component in a syringe



Blunt injection needle for liquid component

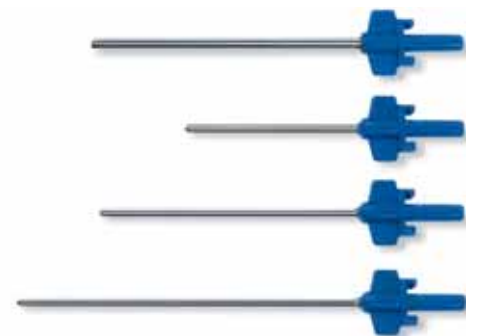


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## Injection cannulas for chronOS Inject

Injection cannulas are available in different lengths and diameters (see Ordering Information).

**Note:** Never use injection cannulas with a diameter smaller than 12 ga.



## Delivery gun for chronOS Inject

- 1 Plastic covers for sliding mechanism
- 2 Reset knob
- 3 Stopping lever
- 4 Handle
- 5 Trigger
- 6 Bayonet catch



## Resetting the feed

Only hold the handle of the delivery gun when resetting the feeder pin. Depress the stopping lever.



Pull the reset knob back to the stop while keeping the stopping lever depressed.



## 1

### Preoperative planning

The work phase constitutes a total of 12 minutes.  
It is divided into the steps described below (see time diagram):

<b>Mix</b>	1 minute	_____
<b>Rest</b>	2 minutes	_____
<b>Apply</b>	3 minutes	_____
<b>Set</b>	6 minutes	_____

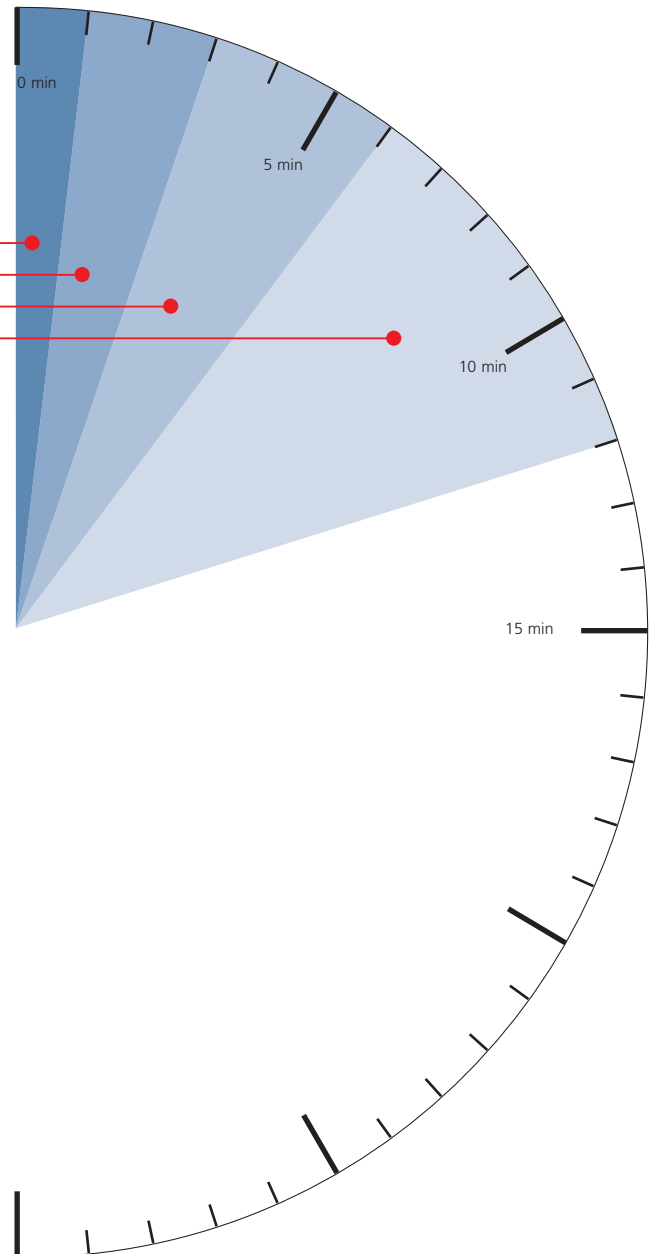
Estimate the volume of the bone defect. If the defect is well enclosed, use a syringe to inject Ringer solution. Next, empty the syringe and aspirate the Ringer solution again. The amount shown on the syringe corresponds approximately to the volume of the defect.

Have ready the packet size of chronOS Inject appropriate for filling the bone defect, the corresponding injection cannula, the delivery gun, and a stopwatch. Take into account the time required for the mixing and application procedures.

**Warning:** chronOS Inject should be stored at a temperature between 5 and 25°C. If the material is stored in a refrigerator please remove it at least 1 hour before its intended use. The processing as well as the hardening of chronOS Inject are temperature dependent and should therefore be performed at room temperature.

The preconditions for a successful treatment of a bone defect with chronOS Inject are:

- a reduced fracture, fixed with stable internal fixation
- a cleared out cavity that is as dry as possible



## 2

### Mixing

Mount the separately packed needle onto the syringe with the liquid component.



Pull the plunger of the cartridge with the powder component back to the stop and remove the blue sealing cap. Do not discard the sealing cap.

**Note:** When using the 10-cc packet, compact the powder by tapping the cartridge on a hard surface.



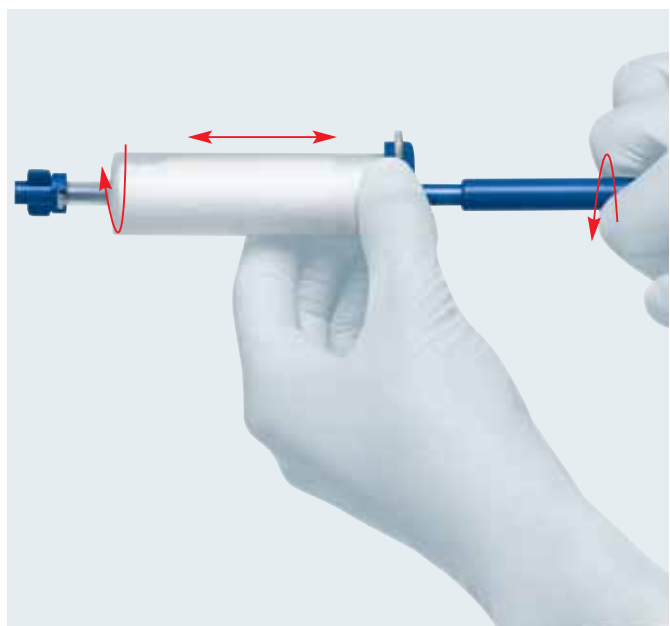
Insert the needle into the cartridge up to stop. Inject the entire liquid component into the cartridge.



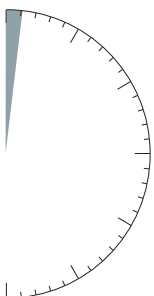
Remove the empty syringe with the needle and replace the blue sealing cap. Lock the bayonet catch.



Mix chronOS Inject by moving the blue plunger back and forth from stop to stop for a minute. Perform the first mixing procedure slowly and with many rotating movements. Then quickly continue mixing. Perform an additional rotating movement at each stop catch.



**Mix 1 minute**



After mixing is completed, pull the plunger out to the back stop catch.



Release the far cartridge seal.

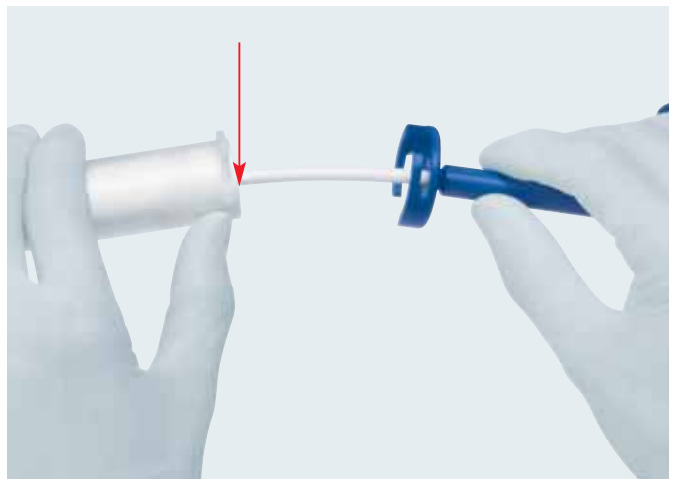


Pull the cartridge seal back as far as possible.



Break the white stirrer off at the predetermined breaking point immediately behind the plunger.

**Note:** When breaking the stirrer, take care to point it away from the operating field and people.

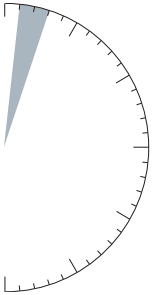


### 3

#### Rest

Place the cartridge in an upright position so that air bubbles can escape upwards. Let the cartridge rest for 2 minutes.

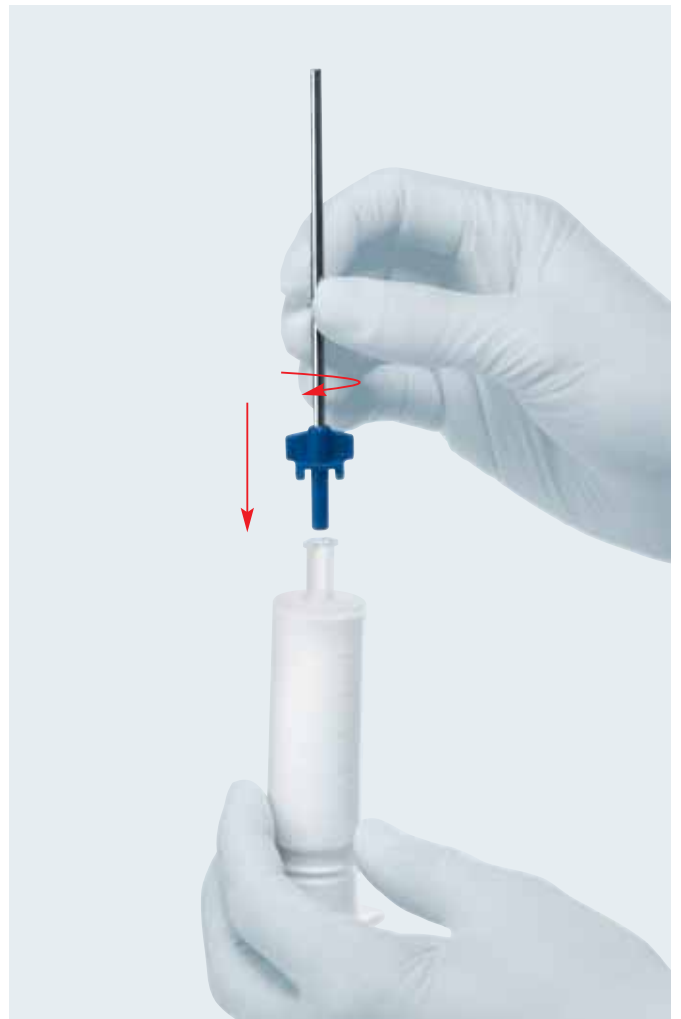
**Rest 2 minutes**



### 4

#### Preparing for the application

Remove the blue sealing cap and mount the appropriate injection cannula.



Load the far end of the cartridge into the bayonet catch of the delivery gun.



Hold the gun with the loaded cartridge upright and expel the remaining air from the cartridge by pressing the gun's trigger several times. As soon as the air has been expelled from the cartridge, chronOS Inject is ready for application.



## 5

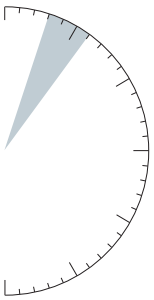
### Application

**Warning:** A stable internal fixation has to be guaranteed before applying chronOS Inject.

For the application, press the lever slowly and uniformly. Do not apply excess pressure.

The time period for injection and – if necessary – shaping of chronOS Inject is 3 minutes. In the treatment of enclosed bone defects, first gain access, reinforce the cavity, do not remove the haematoma and pay attention to completely filling the defect by careful retrograde filling of the cavity.

### Application 3 minutes



The surface of chronOS Inject can be shaped as desired by using a moistened spatula or glove.

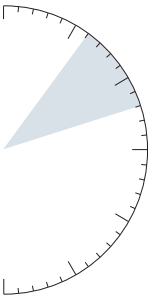


## 6

### Setting

Leave chronOS Inject undisturbed for 6 minutes. Do not touch or shake the implant during the hardening phase, as this could affect the crystallization process and consequently the mechanical properties of chronOS Inject.

### Setting 6 minutes



**Note:** After 6 minutes, chronOS Inject has a primary stability that permits wound closure. Hardening is complete after 24 hours. Avoid any loading of chronOS Inject for the first 24 hours after application.



## Cleaning and Care

Clean and sterilize the delivery gun as soon as possible after use. The plastic covers of the sliding mechanism should be removed beforehand. Do not dismantle the sliding mechanism.

Clean and disinfect the delivery gun as well as the plastic covers. The design permits thorough cleaning and disinfection without further disassembly.

Do not lubricate the sliding mechanism.

Sterilize the delivery gun and the plastic covers in systems designed for this purpose using steam autoclave according to EN554 or national recommendations.

Store the sterilized parts in the system and reinsert the plastic covers on the delivery gun prior to clinical use.



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