chronOS INJECT
BONE VOID FILLER

Injectable, Osteoconductive, Resorbable

Instruments and implants approved by the AO Foundation.
This publication is not intended for distribution in the USA.
This surgical technique is intended for instructions for chronOS Inject Bone Void Filler only. Please refer to manufacturer’s information or instruction for use of other products depicted in images in this surgical technique (e.g. rigid fixation hardware).

Warning
This description alone does not provide sufficient background for direct use of the instrument set. Instruction by a surgeon experienced in handling these instruments is highly recommended.

Processing, Reprocessing, Care and Maintenance
For general guidelines, function control and dismantling of multi-part instruments, as well as processing guidelines for implants, please contact your local sales representative or refer to:
http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance
For general information about reprocessing, care and maintenance of Synthes reusable devices, instrument trays and cases, as well as processing of Synthes non-sterile implants, please consult the Important Information leaflet (SE_023827) or refer to:
http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance
Introduction
chronOS Inject Bone Void Filler is a synthetic calcium phosphate bone substitute. The material is injectable, osteoconductive, and resorbable. Irregular bone defects can be completely filled with chronOS Inject Bone Void Filler using a minimally invasive technique. chronOS Inject Bone Void Filler hardens at physiological temperature.

In its hardened state, the implant is biphasic and consists of a brushite matrix and ß-tricalcium phosphate (ß-TCP) granules. Brushite is a resorbable calcium phosphate (dicalcium phosphate dehydrate). The biphasic structure of chronOS Inject Bone Void Filler ensures its function as a matrix and osseous anchor for the ingrowth of bone cells. This process is called osteoconduction and results in a firm compound of chronOS Inject Bone Void Filler and bone. chronOS Inject Bone Void Filler is resorbed by vital bone cells and substituted by autogenous bone within 6 to 18 months, depending on patient conditions. Resorption takes place radially from the periphery to the center. Due to its composition, chronOS Inject Bone Void Filler is initially radio-opaque.
chronOS Inject Bone Void Filler

**Indications**

chronOS Inject Bone Void Filler is intended to be used as bone void filler or augmentation material where cancellous or cortico-cancellous bone should be replaced. This includes the filling of bone defects in the upper and lower extremities and pelvis in non-load bearing indications only.

In traumatologic and orthopedic applications, the following indications can be treated with chronOS Inject Bone Void Filler:

- Treatment primarily of metaphyseal bone defects, e.g. in the radius, tibia, calcaneus, humerus, femur, and metacarpals
- Reconstructive indications, such as filling of a hollow bone space after removal of cysts or benign tumors

Always apply chronOS Inject Bone Void Filler in an enosseous or subperiosteal way, i.e. in direct contact with vital bone.

The quantity of chronOS Inject Bone Void Filler to be used depends on the size of the bone defect. Defects must be completely filled with chronOS Inject Bone Void Filler; care must be taken to avoid overfilling of the defect in order to ensure tension-free wound closure. To fill one defect, no more than the content of the largest available chronOS Inject Bone Void Filler package (10 cc) should be used. chronOS Inject Bone Void Filler is resorbed and converted into autologous bone within 6 to 18 months, depending on patient conditions.

**Contraindications**

chronOS Inject Bone Void Filler is not for use in the following circumstances:

- Acute and chronic infections in the operation area (bone or soft tissue infections)
- Untreated malignant lymphomas or myelomas
- Defects in the region of the open epiphyseal cartilage
- Open fractures
- Fractures opening into the articulation
- Filling of osteochondral defects
- Pathologies of the calcium metabolism (e.g. endocrinopathies)
- Restricted renal function
- Vertebroplasty and filling of vertebral defects
- Filling of cranial defects, e.g. cranioplasty
- Onlay Augmentations in the cranio-maxillofacial area

chronOS Inject Bone Void Filler is not indicated for use in load bearing and unstable indications unless used in conjunction with appropriate osteosynthesis fixation systems or except if the cortical bone can bear the full load.

**Delivery Needles**

**Intended Use**

The Delivery Needles are intended to be used in conjunction with DePuy Synthes Delivery Devices to deliver DePuy Synthes bone void fillers.

**Indications**

This product is to be used in conjunction with Synthes Delivery Devices. Please reference the delivery device or applicable implant Directions for Use for further information.

**Delivery Device**

**Intended Use**

The Delivery Device is intended to be used in conjunction with chronOS Inject Mixing Cartridge to deliver chronOS Inject Bone Void Filler.
chronOS Inject Bone Void Filler

Precautions
- An application of chronOS Inject in an enclosed defect with access to blood vessels can provoke an embolism and must be avoided.
- Particular care is needed when applying chronOS Inject close to an open articular cavity. Avoid extravasations into the articular space.
- Do not open the package until use.
- Examine the package for damages before using the sterile bone substitute, as they might impair sterility. This applies to both the inner primary and the outer secondary peel-off package. In removing the implant from its package, strictly observe the instructions concerning aseptic procedures.
- Do not attempt to resterilize the unused contents of an opened package, but dispose of it. Resterilization of the chronOS Inject Bone Void Filler powder blend and/or chronOS Inject liquid component can result in product not being sterile, and/or not meeting performance specifications, and/or alters material properties.
- Do not use chronOS Inject Bone Void Filler after expiration of the use-by date printed on the package.
- When preparing chronOS Inject Bone Void Filler for implantation, use exclusively components from one and the same package. Always mix the entire amount of powder mixture and liquid.
- chronOS Inject Bone Void Filler must not be mixed with any additives that are not included in the package.
- Always apply chronOS Inject Bone Void Filler directly from the cartridge and use the delivery needle intended for the application. Never use delivery needles with a diameter inferior to 12 ga (gauge).

Delivery Needles

Warnings
- These needles are supplied sterile. If the packaging appears to be compromised, discard the unit and use another Delivery Needle.
- Dispose of needles in an appropriate medical waste container.
- Do not resterilize. Resterilizing Delivery Needles may compromise the hub mechanical properties and sterility cannot be assured.
The components of chronOS Inject Bone Void Filler are sterile packed. chronOS Inject Bone Void Filler is available in three sizes: 2.5 cc, 5 cc, and 10 cc.

Supplied as:
- Powder Blend in mixing cartridge
- Liquid component in a glass syringe
- Blunt injection needle for liquid component

Delivery needles for chronOS Inject Bone Void Filler
Delivery needles are available in different lengths and diameters (see Ordering Information).
Preoperative planning
The work phase constitutes a total of 12 minutes. It is divided into the steps described below (see time diagram):

- Estimate the volume of the bone defect and select the appropriate packing size. Have ready the packet size of chronOS Inject Bone Void Filler appropriate for filling the bone defect, the corresponding delivery needle, the delivery device, and a stopwatch. Take into account the time required for the mixing and application procedures.

- chronOS Inject Bone Void Filler should be stored at a temperature between 5 and 25°C. If chronOS Inject Bone Void Filler has been stored in the refrigerator, remove it in time to ensure that it has taken on room temperature at the moment of application.

Intraoperative Handling
- To prepare the implant site, remove all inflammatory necrotic tissue and bone fragments, and revive the bone. Keep the regions of endosseous vessel and nerve cords clear to avoid pressure sores.

- Reduce and stabilize the implant site.

- Curette the bone defect completely to produce a cavity or space for chronOS Inject Bone Void Filler. Keep bleeding under control, so that chronOS Inject Bone Void Filler can be injected in an almost dry implant site.
2

Mixing
Prior to attaching the blunt needle, compress the contents by firmly pressing the closed glass syringe plunger-end down on a hard surface. This facilitates easy transfer.

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

Put the blunt injection needle from the chronOS Inject Bone Void Filler pack on the glass syringe with the liquid component.

Draw back the blue handle of the mixing system to the stop and remove the blue closing cap from the cartridge containing the powder mixture; DO NOT dispose of this part.
Fully insert the blunt injection needle into the cartridge to inject the entire liquid component into it.
Remove the empty glass syringe with the blunt injection needle, and replace the blue closing cap onto the cartridge.

Mix chronOS Inject Bone Void Filler by rotating the blue handle from stop to stop for 1 minute.
After mixing is completed, draw the blue handle to the stop.

Unscrew the blue lid.
Draw the blue lid to the handle.

Break off the white stirrer from the cartridge end, while keeping away from the operating field or people.
3

Rest
Place the cartridge upright and wait for 2 minutes.

4

Preparing for the application
Remove the blue closing cap and put on the appropriate delivery needle.
Delivery device for chronOS Inject Bone Void Filler

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 device when resetting the feeder pin. Depress the stopping lever.

Pull the reset knob back to the stop while keeping the stopping lever depressed.
Fix the far end of the cartridge to the bayonet catch of the delivery device. Hold the device with the fixed cartridge upright.

Press the delivery device trigger several times to remove the air from the cartridge and to disengage chronOS Inject Bone Void Filler from the delivery needle.
Application
To prepare the implant site, remove all inflammatory necrotic tissue and bone fragments, and revive the bone. Keep the regions of endosseous vessel and nerve cords clear to avoid pressure sores.

Reduce and stabilize the implant site.

Inject chronOS Inject Bone Void Filler into the bone defect in the course of the next 3 minutes.

Inject chronOS Inject Bone Void Filler with a slow retrograde movement to ensure complete filling of the defect.

Use a dampened glove or a spatula to form the surface of chronOS Inject Bone Void Filler as desired.

Upon and after the application, remove all chronOS Inject Bone Void Filler residues from the soft tissues.
Setting
After the 3-minute application phase, leave chronOS Inject Bone Void Filler undisturbed for 6 minutes.

Avoid touching chronOS Inject Bone Void Filler in this phase.
### ORDERING INFORMATION

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<td>Delivery Device for chronOS Inject</td>
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<td>chronOS Inject Bone Void Filler 2.5 cc</td>
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<td>710.066S</td>
<td>chronOS Inject Bone Void Filler 5 cc</td>
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<td>710.067S</td>
<td>chronOS Inject Bone Void Filler 10 cc</td>
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<td>Delivery Needle 10 ga × 10.0 cm, single pack</td>
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BIBLIOGRAPHY


