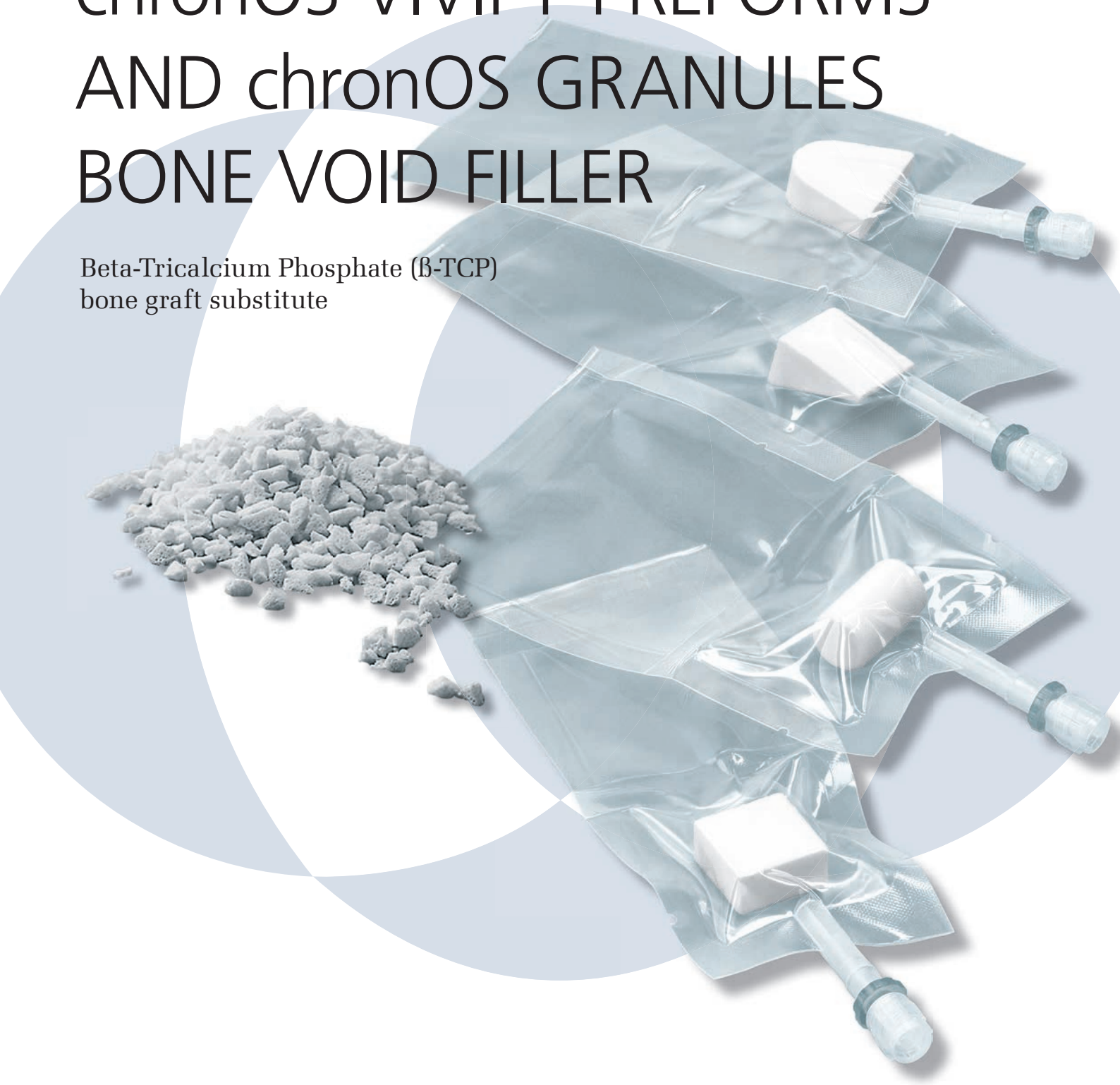
DePuy Synthes

PART OF THE Johnson & Johnson FAMILY OF COMPANIES

chronOS VIVIFY PREFORMS AND chronOS GRANULES BONE VOID FILLER

Beta-Tricalcium Phosphate (ß-TCP)
bone graft substitute



Instruments and implants approved by the AO Foundation.
This publication is not intended for distribution in the USA.

SURGICAL TECHNIQUE

BIOMATERIALS

SOLUTIONS BY DEPUY SYNTHES

Image intensifier control

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

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INTRODUCTION

chronOS Bone Void Filler implants are widely used as synthetic, resorbable and osteoconductive bone graft substitutes for indications in trauma, spine and cranio-maxillofacial surgery.

chronOS Bone Void Filler is a highly porous matrix made of pure ß-tricalcium phosphate. The structural and chemical properties as well as its compressive strength are similar to that of cancellous bone. Due to its composition, chronOS Bone Void Filler is initially radio-opaque.

To fit precisely into bony defects, chronOS Bone Void Filler is available as granules of different sizes (Fig. 1) and as pre-shaped cylinders, blocks and wedges in a pouch as chronOS Vivify Preforms Bone Void Filler (Fig. 2). Furthermore, cages pre-filled with chronOS Bone Void Filler are available as vertebral interbody fusion implants. Having a synthetic origin, chronOS Bone Void Filler offers the advantage of uniform quality and unlimited availability. It avoids donor site morbidity and shortens the duration of the overall surgery. Therefore, chronOS Bone Void Filler is a good alternative to autologous bone.[1–5]

In addition, chronOS Bone Void Filler implants show excellent biocompatibility which was demonstrated according to the standards of the ISO 10993 series. Safety and biocompatibility of the products are further supported by 25 years of clinical application with no reported adverse reactions.[6–10]

Fig. 1: chronOS Granules Bone Void Filler

Fig. 2: chronOS Vivify Preforms Bone Void Filler

ENGINEERED FOR OSTEOCONDUCTIVITY

Optimized scaffold

Osteoconductivity is a prerequisite for successful bone remodelling. It is mainly influenced by three factors: the overall porosity, the interconnected macropores and the micropores. chronOS Bone Void Filler has been designed to optimize these features in order to mimic cancellous bone and provide an ideal scaffold for bone tissue infiltration.[11,13]

Overall porosity

chronOS Bone Void Filler has a total porosity of 60% ±3 for the granules and 72% ±6 for the preformed shapes. chronOS Bone Void Filler benefits from a good compromise between porosity and mechanical stability.

Interconnected macropores

The size of the macropores of chronOS Bone Void Filler are distributed mainly within a range of 100 to 500 µm (Fig. 3,4). This provides the optimal condition for vascularization and migration of osteoclasts and osteoblasts. In addition, the macropores are interconnected to allow bone formation throughout the entire implant.[12–16]

Micropores

chronOS Bone Void Filler contains micropores, which are defined as the space within the material smaller than 10 µm. The microporosity accelerates the remodeling process by increasing the surface area and allowing for circulation of body fluids.[12–16] (Fig. 5)

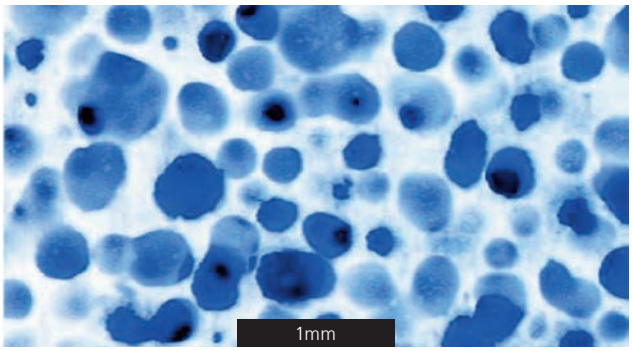


Fig. 3: chronOS Bone Void Filler macrostructure

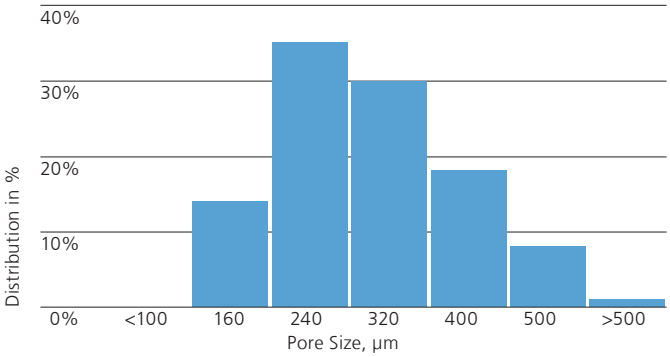


Fig. 4: Distribution of the size of chronOS Bone Void Filler macropores

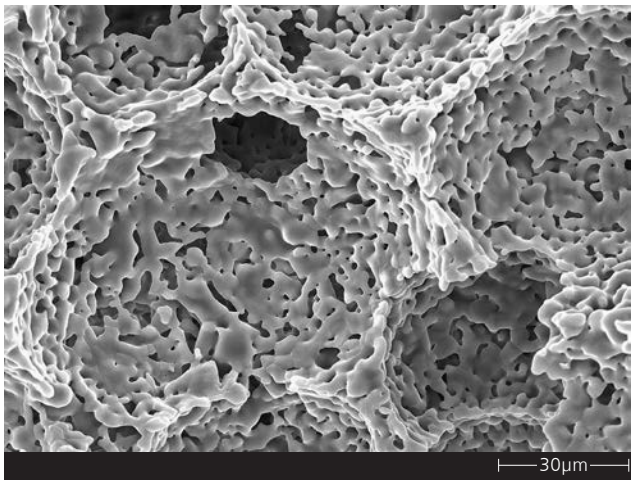


Fig. 5: chronOS Bone Void Filler microstructure*

* Microstructure of chronOS Bone Void Filler (Source: Dr. M. Bohner, RMS Foundation; Dr. G. Richards, AO Research)

FAST REMODELING WITHIN 6 TO 18 MONTHS

Rapid resorption of β-tricalcium phosphate

Differences in chemical composition of biomaterials have profound effects on their in vivo behavior. chronOS Bone Void Filler consists of pure β-tricalcium phosphate and is structurally and chemically similar to bone. Osteoclasts resorb chronOS Bone Void Filler like natural bone. β-tricalcium phosphate is resorbed faster than hydroxyapatite. A study showed that the fraction of total defect volume after 24 months is 5.8% for chronOS Bone Void Filler whereas it is 30.6% for hydroxyapatite (Fig. 6).[17–22]

Formation of new host bone

While resorption is taking place, new bone is being formed: osteoblasts fill the lacunae created by osteoclast by producing extracellular matrix, which is subsequently calcified. As a result of both the choice of the specific chemical composition and the optimized scaffold as described previously, chronOS Bone Void Filler showed faster and more effective formation of new bone in a 5-wall defect model tested in an animal study than other bone graft substitutes (Fig. 7).[16,17]

Replaced in 6 to 18 months

The key to success of chronOS Bone Void Filler is the remodeling process. Resorption and new bone formation happen simultaneously.[16] Timing is the critical factor for a bone graft to remodel into natural bone. If the resorption is too rapid, the osteoblasts lose the scaffold needed for the formation of new bone. If the resorption is too slow or incomplete, the graft will not be replaced by bone in an adequate time span.[21–22] It is being replaced in the human body by host bone in 6 to 18 months; depending on the indication and the patient's conditions (Fig. 8).[15,16]

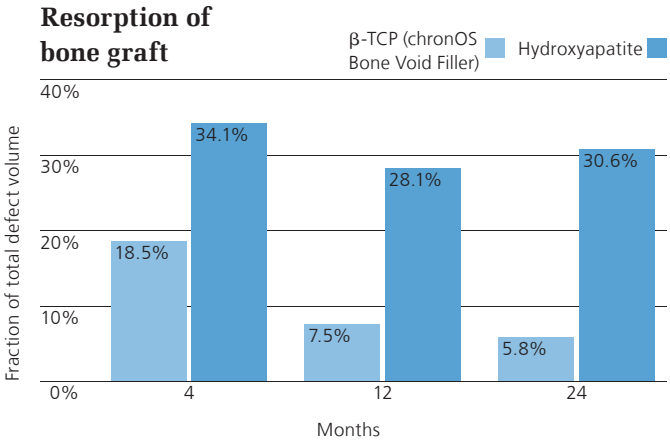


Fig. 6: Resorption of β-tricalcium phosphate (chronOS Bone Void Filler) is significantly faster than for hydroxyapatite in an animal model.[17]

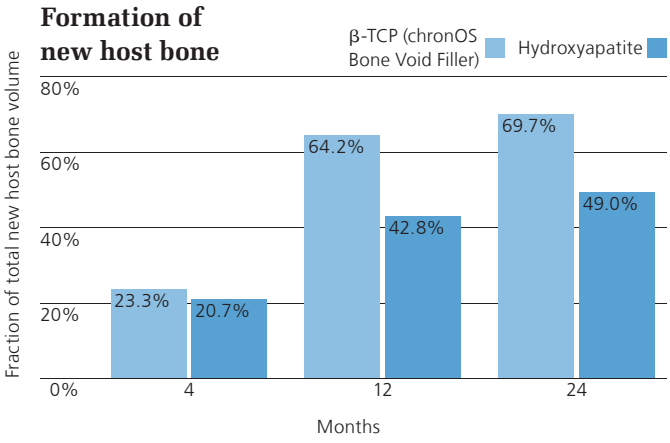


Fig. 7: β-tricalcium phosphate (chronOS Bone Void Filler) is remodeled faster and more efficiently into new host bone than hydroxyapatite in an animal model.[17]

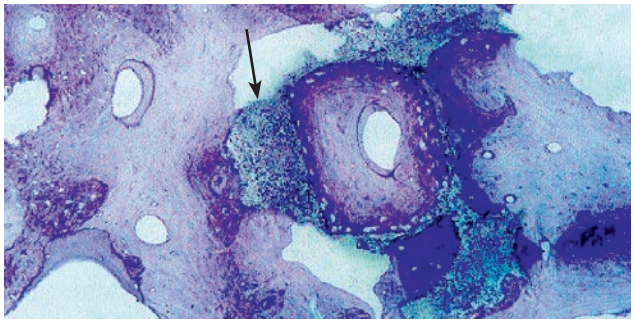


Fig. 8: Remodeling and substitution of chronOS Bone Void Filler (24 weeks in an animal model). Some chronOS Granules Bone Void Filler are still lined by woven bone, other parts are directly covered by lamellar bone, or are exposed to the marrow space (arrow) where they undergo degradation by osteoclasts.[17]

ENHANCING chronOS BONE VOID FILLER WITH BIOLOGICAL FACTORS

Impregnation of the porous material with bone marrow or blood introduces blood cells, growth factors and, in the case of bone marrow, osteoprogenitor cells into the bone graft substitute. The combination of chronOS Bone Void Filler with bone marrow accelerates and enhances osteointegration and is a valuable alternative to autologous or allogenic bone graft material.[23,24]

In order to make the osteoinductive and osteogenic potential of autologous bone marrow available, DePuy Synthes has developed the Perfusion Concept allowing the efficient, intra-operative vacuum impregnation of chronOS Vivify Preforms Bone Void Filler with the patient's own bone marrow or blood. Perfusion under vacuum is required to force the air out of the pores and bring the viscous fluid into the center of chronOS Vivify Preforms Bone Void Filler (Fig. 9). Simple dipping of the ceramic material in bone marrow or blood only leads to a superficial impregnation at the borders.[23,24]

With chronOS Vivify Preforms Bone Void Filler, the implants come in special perfusion pouches. According to their size, chronOS Vivify Preforms Bone Void Filler are pre-packaged in either a small or large perfusion pouch (Fig. 10, 11). The Perfusion Concept, by which the osteoconductive chronOS Vivify Preforms Bone Void Filler are provided with the osteoinductive and osteogenic potential of blood or bone marrow aspirate, is completed by using the Bone Access Needles (Fig. 12) for aspiration of bone marrow.

The Bone Access Needle (BAN) is a sterile-packed 11 gauge, tapered Jamshidi style needle (diamond tip and bevelled tip) with a Luer lock fitting available in 10 and 15 cm lengths. Standard Luer lock syringes (recommended volume = 20 mL) are compatible with the other components of the Perfusion Concept allowing a direct transfer of the bone marrow or blood into the perfusion pouch containing the chronOS Vivify Preforms Bone Void Filler.

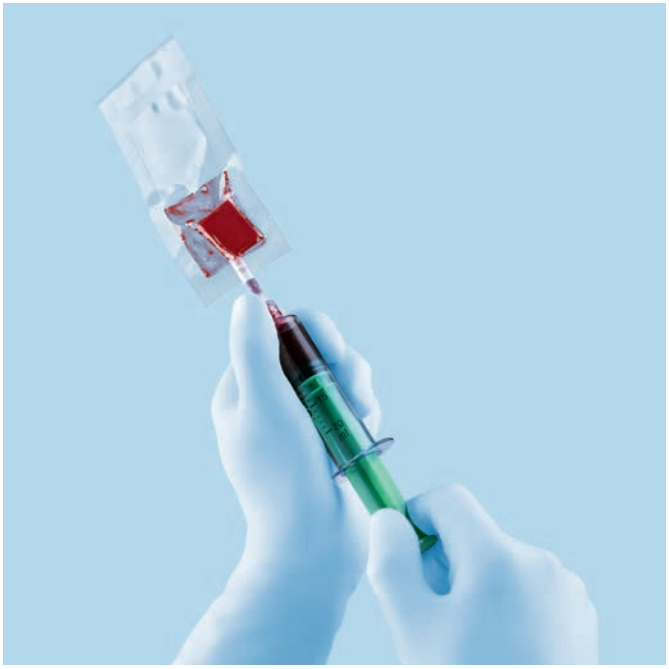


Fig. 9: Perfusion of a chronOS Vivify Preform Bone Void Filler

Fig. 10: Small perfusion pouch

Fig. 11: Large perfusion pouch

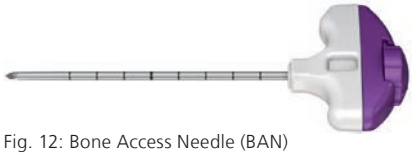


Fig. 12: Bone Access Needle (BAN)

FEATURES AND BENEFITS

Feature	Benefit
Osteoconductive	Provides a scaffold for bony ingrowth
Fully synthetic	No risk of disease transmission from human tissue
Interconnected macro- and micropores (60 or 72 % porous)	• Optimal environment for vascularization and bony infiltration • Increases surface area where new bone forms and allows circulation of fluids throughout the implant
Remodels in 6–18 months	Remodeling rate is similar to the rate of regeneration of new bone
Radiopaque	Enables visualization of implant position
Can be mixed with blood and bone marrow aspirate (BMA)	Osteogenic cells and growth factors are naturally found in BMA
Ready to use off the shelf	• Avoids morbidity and risk of complications from second surgical site • Sufficient quantity of bone graft substitute • Shortens OR time

ANIMAL STUDY – PERFUSION WITH BLOOD VS. BONE MARROW

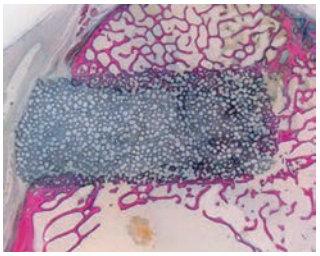
An animal study was performed to evaluate the osteogenic potential of autologous substances like bone marrow and blood processed intraoperatively and combined with a synthetic ceramic bone substitute.

Critical size defects (8.5 mm cylindrical, 20 mm length) were surgically created on the left and the right tibia metaphysis of adult sheep. The artificial defects were filled with chronOS Bone Void Filler cylinders that were either perfused with blood or bone marrow. Resorption of chronOS Bone Void Filler and regeneration of host bone was analyzed histologically at 6 and 12 weeks postoperative.

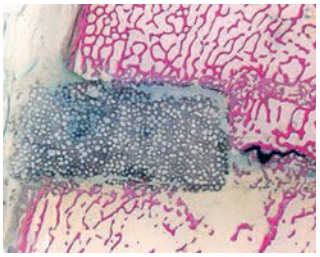
Osteointegration was significantly more pronounced for chronOS Bone Void Filler implants impregnated with bone marrow rather than with blood. After 12 weeks, most of the chronOS Bone Void Filler implant was remodeled into host bone when bone marrow was used, whereas the bone substitute material was still clearly visible when impregnated with blood.[23,24]

6 weeks post-op

Blood

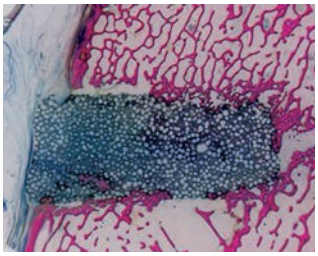


Bone marrow

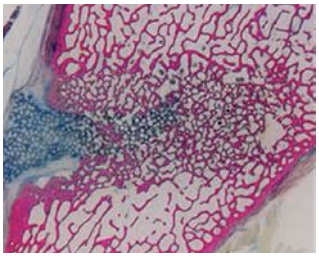


12 weeks post-op

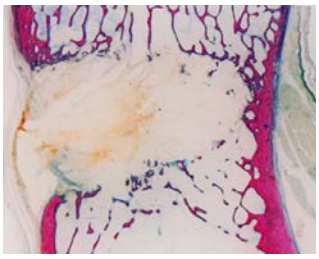
Blood



Bone marrow



Empty Defect (control group)



INTENDED USE, INDICATIONS AND CONTRAINDICATIONS

Intended use
chronOS Bone Void Filler implants are a bone replacement material of synthetic, porous and resorbable β-tricalcium phosphate (β-TCP). In its function as temporary bone substitute, it serves to fill and bridge bone defects in children, adolescents and adults.

Indications
chronOS Bone Void Filler implants should be used as bone void fillers or augmentation material in zones requiring cancellous rather than cortical bone. This includes the filling of bone defects after trauma, reconstruction or correction in non-load bearing indications only.

The porous structure of chronOS Bone Void Filler implants acts as a matrix for the ingrowth of bone. chronOS Bone Void Filler implants must always be applied by enosseal or subperiosteal implantation, i.e. by direct contact with the vital bone.

As a general rule, it is recommended that small granules are used in small defects and larger granules in larger bone defects:
- 0.5–0.7 mm granule size for filling defects up to 1.0 cc
- 0.7–1.4 mm granule size for filling defects up to 2.5 cc
- 1.4–2.8 mm and 2.8–5.6 mm granule size for filling defects from 2.5 cc

The implant must completely fill the bone defect (press-fit). However, it is essential to avoid overfilling to ensure tension-free wound closure. It is recommended that the filled defects are covered with a periost flap or a resorbable sheet to avoid soft tissue infiltration.

A mixture with autologous and/or allogenous bone is highly recommended for larger defects (more than 20 cc). The size of the chronOS Bone Void Filler implant used depends on the size of the bone defect.

As a rule, chronOS Bone Void Filler implants are resorbed within 6 to 18 months and converted into bone; depending on patient conditions.

Contraindications
chronOS Bone Void Filler implants should not be used in the following circumstances:
- Acute and chronic infections in the operation area, e.g. inflammation, bacterial bone diseases (posttraumatic or chronic osteomyelitis) and soft-tissue infections
- Malignant myeloma, Burkitt's lymphoma, and other lymphomas
- Defects and fractures in the region of an open epiphysis
- Osteoporosis
- Severe instability or deformation at the extraction point (harvesting site)
- Load bearing and unstable applications

CONDITIONAL RESTRICTIONS AND WARNINGS

Conditional restrictions

The use of chronOS Bone Void Filler implants has a more restricted indication in:

- Severe, endocrine-induced bone diseases (e.g. hyperparathyroidism)
- Current therapy with steroids and with drugs, which intervene in calcium metabolism (e.g. calcitonin)
- Severe, poorly controlled diabetes (diabetes mellitus) with bad wound healing tendencies
- Immunosuppressive therapy
- Poor bone quality

The use of chronOS Bone Void Filler implants is not known in:

- Cardiovascular diseases
- Pregnancy and lactation period
- Filling of bone defects in congenital deformations
- Immunosuppressive or radiation therapy
- Compromised immune system, compromised wound healing

Warnings

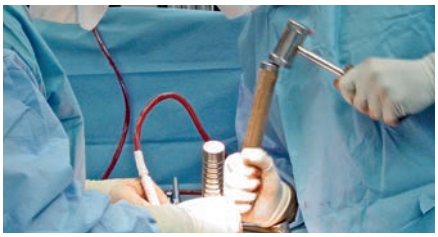
- **Do not use chronOS Bone Void Filler implants as a stand-alone product unless the cortical bone can bear the full load. Maximum mechanical stability in filling the defect with chronOS Bone Void Filler implants is a prerequisite for a good bony incorporation. If there is instability, use appropriate internal fixation to first stabilize the operating area.**
- **Do not use 2.8–5.6 mm granule size for filling of sinus lifts.**
- **Do not attempt to re-sterilize the unused contents of an opened pack, but dispose of such remnants. Re-sterilizing of chronOS Bone Void Filler implants can result in product not being sterile and/or meet performance specifications.**
- **Do not fix chronOS Bone Void Filler implants with screws or tacks directly in the bone.**
- **The perfusion pouch is intended for the impregnation of chronOS Vivify Preforms Bone Void Filler with bone marrow or blood.**
- **chronOS Inserts Bone Void Filler for Cervios must only be used in combination with Synthes Cervios Interbody Fusion Devices.**
- **Do not exceed the recommended upper volume limit as this may over pressurize the perfusion pouch.**

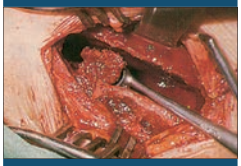
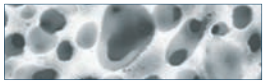
OVERVIEW

Step 1
Aspiration of bone marrow

Step 2
Perfusion under vacuum

Step 3
Implantation of chronOS Vivify Preforms Bone Void Filler



	chronOS Bone Void Filler implants without perfusion of bone marrow	chronOS Vivify Preforms Bone Void Filler perfused with bone marrow	Demineralized Bone Matrix (DBX*)	Autograft
				
Biological property:	**Osteoconductive**	**Osteopromotive**	**Osteoinductive**	**Osteogenic**
Matrix 	+++	+++	+++	+++
Growth factors 	–	+	+++	+++
Osteoprogenitor 	–	+	–	+++

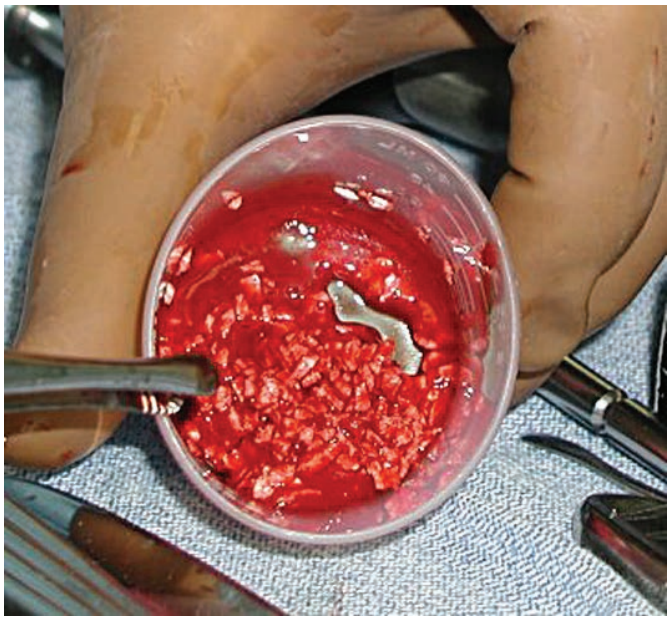
*DBX is an allograft facilitated by DePuy Synthes. The availability of DBX is subject to country specific regulations. Please contact your local sales representative for further details.

Surgical considerations
chronOS Vivify Preforms Bone Void Filler
chronOS Vivify Preforms Bone Void Filler must always be applied by enosseal or subperiosteal implantation, i.e. by direct contact with the vital bone.

It is recommended to aspirate bone marrow and to prepare the chronOS Vivify Preform Bone Void Filler/bone marrow combination directly before implantation. However, if required, bone marrow (BM) can be harvested prior to using the chronOS Vivify Preform Bone Void Filler/bone marrow hybrid implant. In this case it is recommended to combine the aspirated bone marrow immediately with the chronOS Vivify Preform Bone Void Filler before clotting occurs. Implant chronOS Vivify Preforms Bone Void Filler immediately or place in a sterile bowl for later use during the same surgical procedure.

Two Bone Access Needles (page 17) can be used as access instruments for the aspiration of autologous bone marrow. The syringe (not provided with chronOS Bone Void Filler implants) needed for the aspiration and the perfusion in the perfusion pouch should have a volume of at least 20 mL, feature a standard Luer fitting and be approved for the aspiration of blood/autologous bone marrow.

Surgical considerations
chronOS Granules Bone Void Filler
It is useful to mix chronOS Granules Bone Void Filler with autologous bone marrow or blood for improved handling. Introduce the resulting mixture into the defect. During application, remove individually displaced granules from the soft tissue. Based on experimental and clinical data it is considered as safe to mix chronOS Granules Bone Void Filler with autologous or allogenic bone.



PERFUSION OF chronOS VIVIFY PREFORMS BONE VOID FILLER

Optional system

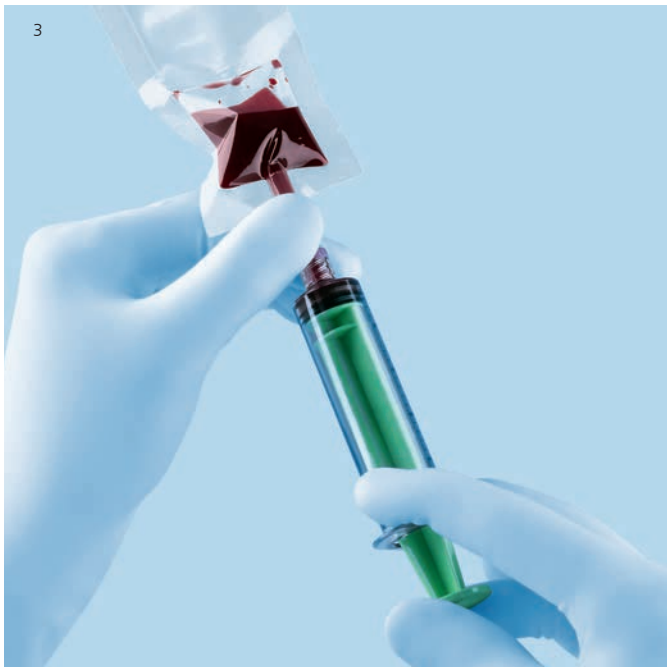
03.702.241S	Bone Access Needle, diamond tip, 11G front-opening cannula, 100 mm, violet, pack of 1 unit, sterile
03.702.244S	Bone Access Needle, diamond tip, 11G front-opening cannula, 150 mm, violet, pack of 1 unit, sterile

Perfuse chronOS Vivify Preforms Bone Void Filler
Aspirate bone marrow using a Bone Access Needle or fill a syringe with the patient's blood.

Unscrew the protective cap on the perfusion pouch. (1)

Attach the syringe containing autologous bone marrow or blood to the chronOS Vivify perfusion pouch using the port with the Luer fitting. (2)

Fill the perfusion pouch with medium of choice following the recommended volume ranges to ensure adequate wetting of the chronOS Vivify Preforms Bone Void Filler surface. (3)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Recommended volumes for perfusion of chronOS Vivify Preforms Bone Void Filler:

chronOS Vivify Cylinders Bone Void Filler

∅ (mm)	Perfusion Pouch	Perfusion Volume Range (mL)
8.5	Small	5–8
9.5	Small	5–8
10.5	Small	5–8
12.5	Large	8–10
14.0	Large	8–10

chronOS Vivify Blocks Bone Void Filler

Size (mm)	Perfusion Pouch	Perfusion Volume Range (mL)
5×5×10	Small	2–5
12.5×12.5×10	Small	5–8
20×20×10	Small	8–10

chronOS Vivify Wedges Bone Void Filler

Angle	Perfusion Pouch	Perfusion Volume Range (mL)
10°	Small	5–8
14°	Small	8–10
18°	Small	8–10
22°	Large	8–10
26°	Large	8–10

chronOS Vivify Wedges Bone Void Filler, semi-circular

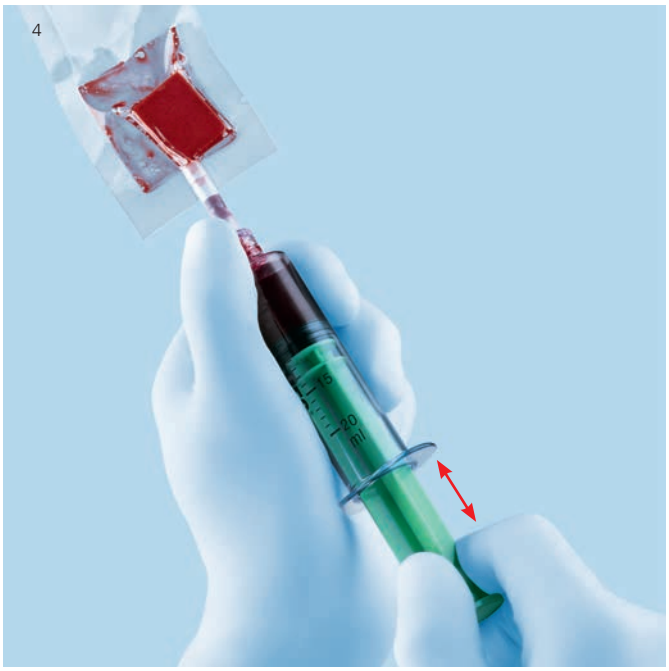
Angle	Perfusion Pouch	Perfusion Volume Range (mL)
7°	Large	8–10
10°	Large	8–10
13°	Large	10–12

Do not exceed the recommended upper volume limit as this may over pressurize the perfusion pouch.

Perfuse chronOS Vivify Preforms Bone Void Filler by gently pumping the syringe plunger 10 to 12 times.

Allow a flow back of bone marrow or blood into the syringe before pumping it again into the pouch. (4)

Do not pull the syringe plunger back to its maximum stroke as this may cause the plunger to disengage from the syringe barrel, resulting in the loss of the syringe contents.

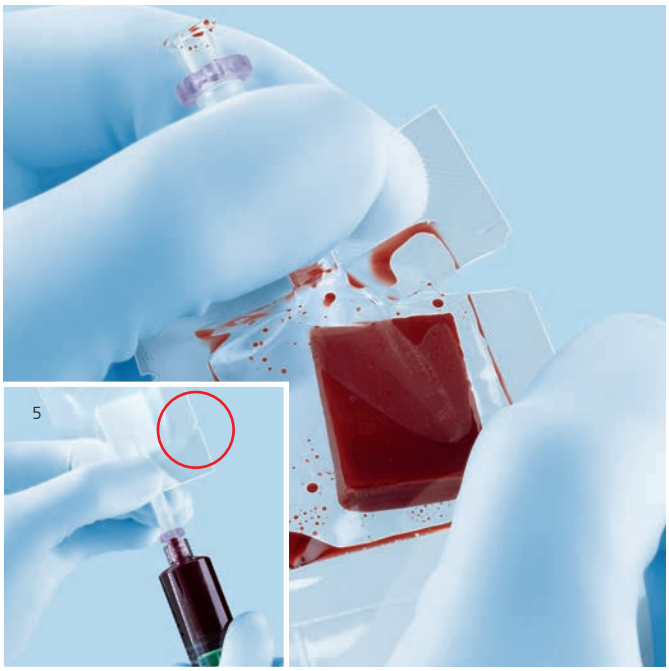


REMOVAL OF chronOS VIVIFY PREFORMS BONE VOID FILLER FROM PERFUSION POUCH

Remove the syringe to relieve any pressure from the perfusion pouch.

When ready to use the implant, remove it by grasping the implant through the perfusion pouch to secure it, while tearing at the designated notch (5).

Implant chronOS Vivify Preforms Bone Void Filler immediately or place in a sterile bowl for later use during the same surgical procedure.



PRODUCT INFORMATION

chronOS Vivify Cylinders Bone Void Filler

Art. No.	∅ (mm)	Length (mm)	Perfusion Pouch
07.720.030S	8.5	25	Small
07.720.031S	9.5	25	Small
07.720.032S	10.5	25	Small
07.720.033S	12.5	25	Large
07.720.035S	14.0	25	Large

chronOS Vivify Blocks Bone Void Filler

Art. No.	Size (mm)	Perfusion Pouch
07.720.042S	5×5×10	Small
07.720.045S	12.5×12.5×10	Small
07.720.047S	20×20×10	Small

chronOS Vivify Wedges Bone Void Filler

Art. No.	Angle	Size (mm)	Perfusion Pouch
07.720.050S	10°	25×20×6	Small
07.720.051S	14°	25×20×8	Small
07.720.052S	18°	25×20×10	Small
07.720.053S	22°	25×20×12	Large
07.720.054S	26°	25×20×14	Large

chronOS Vivify Wedges Bone Void Filler, semi-circular

Art. No.	Angle	Size (mm)	Perfusion Pouch
07.720.057S	7°	25×35×7	Large
07.720.060S	10°	25×35×10	Large
07.720.063S	13°	25×35×13	Large

chronOS Granules Bone Void Filler are not offered in a perfusion pouch. They can easily be combined with autologous bone marrow or blood in a sterile bowl.

chronOS Granules Bone Void Filler*

Art. No.	∅ (mm)	Content (mL)
710.000S	0.5–0.7	0.5
710.001S	0.7–1.4	0.5
710.002S	0.7–1.4	1.0
710.003S	0.7–1.4	2.5
710.011S	1.4–2.8	2.5
710.014S	1.4–2.8	5.0
710.019S	1.4–2.8	10.0
710.021S	1.4–2.8	20.0
710.024S	2.8–5.6	2.5
710.025S	2.8–5.6	5.0
710.026S	2.8–5.6	10.0
710.027S	2.8–5.6	20.0

* Not available in perfusion pouch

Bone Access Needle**

03.702.241S	Diamond tip, 11G front-opening cannula, 100 mm, violet, pack of 1 unit, sterile

03.702.244S	Diamond tip, 11G front-opening cannula, 150 mm, violet, pack of 1 unit, sterile

** Bone Access Needle CE0482, manufactured by: Möller Medical GmbH, Wasserkuppenstrasse 29–31, 36043 Fulda, Germany
Distributed by: Synthes GmbH, Eimattstrasse 3, 4436 Oberdorf, Switzerland

Also available:

chronOS Inserts Bone Void Filler for Cervios chronOS, wedge-shaped

Art. No.	Height	Fits to Cervios cage
710.921S	5 mm	889.921S
710.922S	6 mm	889.922S
710.923S	7 mm	889.923S
710.924S	8 mm	889.924S
710.925S	9 mm	889.925S
710.926S	10 mm	889.926S

chronOS Inserts Bone Void Filler for Cervios chronOS, curved

Art. No.	Height	Fits to Cervios cage
710.931S	5 mm	889.931S
710.932S	6 mm	889.932S
710.933S	7 mm	889.933S
710.934S	8 mm	889.934S
710.935S	9 mm	889.935S
710.936S	10 mm	889.936S

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Autologous bone grafting is associated with several shortcomings and potential complications. chronOS Bone Void Filler is an advantageous alternative to bone harvesting.

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Optimized scaffold

To induce the bone remodeling process, osteoconductivity must occur. It is mainly influenced by three factors:

i) The overall porosity:
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ii) The interconnected macropores:
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iii) Micropores:
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chronOS Bone Void Filler induces remodeling process

The remodeling process (simultaneous resorption and new bone formation) is possible due to the specific chemical composition and the optimized scaffold of chronOS Bone Void Filler. chronOS Bone Void Filler consists of pure ß-tricalcium phosphate which remodels completely.

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Enhancing chronOS Bone Void Filler with biological properties

The biological characteristics of chronOS Bone Void Filler can be improved by combining chronOS Bone Void Filler with patient bone marrow or blood, making chronOS Bone Void Filler potentially osteoinductive or osteogenic, respectively.

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