Bicon SynthoGraft
Summary of Safety and Clinical Performance for the Healthcare Professional

Document number: SSCP-002
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The Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the device. The following information is intended for users/healthcare professionals.

The SSCP is not intended to replace the Instructions For Use (IFU) as the main document to ensure the safe use of the device, nor is it intended to provide diagnostic or therapeutic suggestions to intended users or patients.

1. Device identification and general information

1.1 Device trade name(s)
SynthoGraft
SynthoGraft Pure Phase Beta-Tricalcium Phosphate
SynthoGraft β-TCP
SynthoGraft Beta-TCP

1.2 Manufacturer's name and address
Bicon, LLC
501 Arborway
Boston, MA 02130 USA

1.3 Manufacturer's single registration number (SRN)
US-MF-000002782

1.4 Basic UDI-DI
081311002SYN9L

1.5 Medical device nomenclature description / text
The European Medical Device Nomenclature (EMDN) and Classificazione Nazionale dei Dispositivi Medici (CND) code and descriptor for SynthoGraft is listed in Table 1.

Table 1 – Medical Device Nomenclature

EMDN/CND Code	Term	Definition
Q010302	Synthetic bone graft	An artificial bone substitute used for structural bone replacement typically when bone is lost due to disease (e.g., osteoporosis) or injury. It consists mainly of porous and mesh ceramic materials that provide a framework for bone growth, or harvested sea coral that serves as an additive, extender, or provides a framework for bone growth. This is a single-use device.

1.6 Class of device
Class III

1.7 Year when the first (CE) was issued covering the device
2009

1.8 Authorized representative is applicable; name and the SRN
Bicon Europe, Ltd.
Unit 4 Ballycummin Village
Ballycummin, Limerick
Ireland
SRN: IE-AR-000002497

1.9 NB's name and the NB's single identification number
BSI Group The Netherlands B.V.
Say Building, John M. Keynesplein 9, 1066 EP
Amsterdam
Netherlands
Notified Body number: 2797

2. Intended use of the device

2.1 Intended purpose
The intended purpose of SynthoGraft is to provide a matrix for bone augmentation in maxillary and mandibular bone.

2.2 Indication(s) and target population(s)
The target population is edentulous or partially edentulous patients. The specific anatomical location is the bone that forms the oral cavity. The intended users of the device are dentists who ultimately place the device surgically.

SynthoGraft is designed for:

- the filling and/or reconstruction of either traumatic or degenerative multi-wall bone defects.
- the augmentation of the sinus floor.
- the augmentation of alveolar ridges.
- the filling of periodontal or other alveolar bone defects and tooth sockets and osteotomies.
- the preservation of the alveolus for the preparation of an implant site.

2.3 Contraindications and/or limitations
SynthoGraft should not be used for patients with juvenile form of chronic periodontitis, uncontrolled systemic diseases, infections, endocrinopathies, coagulation deficiencies, psychological and neurological problems, or in any other instance where the clinician believes that surgery or the use of SynthoGraft is inappropriate.

3. Device description

3.1 Description of the device

SynthoGraft is a synthetic, biocompatible, and resorbable granulate ceramic made of pure phase beta-tricalcium phosphate ($Ca_3(PO_4)_2$) which is used as a matrix for bone augmentation. SynthoGraft is available in 50-500µm (micrometer) and 500-1000µm particle sizes in vials ranging from 0.25 grams (g) to 2.0g with smaller particle sizes for smaller defects and larger particle sizes for larger defects. SynthoGraft is used by dentists for patients who would benefit from bone augmentation, such as edentulous or partially edentulous patients.

Principle of Operation

SynthoGraft is an inorganic calcium phosphate compound that is placed in a bone void typically after tooth extraction for the repair of bony defects. The structure of SynthoGraft, including its porosity, allows for new bone growth as the SynthoGraft is resorbed by the body. After an appropriate healing period, the patient ideally will have generated enough bone to be able to place a dental implant.

Key Functional Elements

The particle size is key when considering the size of the bone defect. A larger particle size would more easily fill up a larger defect though the smaller particle size could also be used. Another key to the functionality of SynthoGraft is its composition of calcium phosphate which is the same as the main mineral found in bone.

SynthoGraft is packaged and sterilized via gamma irradiation for single use only.

The catalog/model numbers of SynthoGraft as covered by this SSCP are shown in Table 2.

Table 2 – Product Codes and Device Configurations

Catalog Number	Description	Particle Size	Grams (g)/ Vial	# of Vials	Total Grams (g)
260-400-125	SynthoGraft .25g (50-500um) x5	50-500um	0.25g	5	1.25g
260-400-150	SynthoGraft 0.5g (50-500um) x5	50-500um	0.5g	5	2.5g
260-400-151	SynthoGraft 1.0g (50-500um) x5	50-500um	1.0g	5	5.0g
260-400-152	SynthoGraft 2.0g (50-500um) x5	50-500um	2.0g	5	10g
260-400-525	SynthoGraft .25g (500-1000um) x5	500-1000um	0.25g	5	1.25g
260-400-500	SynthoGraft 0.5g (500-1000um) x5	500-1000um	0.5g	5	2.5g
260-400-501	SynthoGraft 1.0g (500-1000um) x5	500-1000um	1.0g	5	5.0g
260-400-502	SynthoGraft 2.0g (500-1000um) x5	500-1000um	2.0g	5	10g

3.2 A reference to previous generation(s) or variants if such exist, and a description of the differences

There are no previous generations of the device produced. The devices currently produced are the same design as produced previously.

3.3 Description of any accessories which are intended to be used in combination with the device

SynthoGraft may be delivered using a bone graft syringe which may be obtained separately but is not required for SynthoGraft use. The bone graft syringe is a Class I device. It is a non-surgically invasive device intended for transient use in the oral cavity.

3.4 Description of any other devices and products which are intended to be used in combination with the device

Dental sutures shall be used to close the surgical site after SynthoGraft placement to prevent particle migration. A resorbable collagen membrane is recommended for lateral sinus lifts to aid in post-surgery wound healing, however it is not required.

4. Risks and warnings

4.1 Residual risks and undesirable effects

- Rejection of the grafting material or allergic reaction
- Lack of osseointegration
- Bone loss
- Infection
- Inflammation, swelling or pain at the placement site
- Delayed healing

Per the clinical evaluation report, where the data was sourced from an annual systematic review of scientific literature on the actual SynthoGraft device, while there were instances of failure, there have been no reported occurrences of harm from these residual risks or undesirable effects at any time from implantation to the time where a dental implant was placed, typically within 6 months with follow-up to 4 years. All known and foreseeable hazards and associated risks have been identified and reduced as far as possible, and the residual risks are deemed acceptable.

4.2 Warnings and precautions

Warnings

- SynthoGraft should be used only by or under the supervision of trained personnel with experience with the surgical techniques associated with biomaterials.
- SynthoGraft is packaged and sterilized via gamma irradiation for single use only.
- Do not apply SynthoGraft dry. It must be wetted with the patient's blood. Too much blood may cause particle migration.
- Do not saturate SynthoGraft with any liquid other than the patient's blood.
- Do not re-sterilize SynthoGraft.
- Discard any unused SynthoGraft granulate. Re-use of SynthoGraft may cause adverse reactions, including, but not limited to, infection, inflammation, or other injury.
- SynthoGraft is not intended for immediate loading.
- Do not overfill defect site.
- Secure SynthoGraft to prevent migration of materials.
- Do not use if package has been opened, damaged, or if the expiration date has passed.
- Do not compromise blood supply to the defect area.
- Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established, if applicable.

Precautions

Under no circumstance should SynthoGraft be applied in a dry state. It must be wetted with blood. Similarly, SynthoGraft should not be saturated with any solution (e.g. physiological saline, NaCl, or antibiotics) other than the patient's own blood. Patients undergoing antiresorptive therapy, such as bisphosphonate use, should consult their doctor before use of the device. Patients should be given an implant card allowing the identification of the device including device name, lot number, UDI, model, and name, address, and website of the manufacturer.

The general caution statement in the labeling for the devices in the SynthoGraft family is as follows:

> **Rx Caution**: USA Federal law restricts this device to sale by or on the order of a licensed dentist.

4.3 Other relevant aspects of safety, including a summary of any field safety corrective action (FSCA including FSN) if applicable

There has not been any Field Safety Corrective Action (FSCA), Field Safety Notice (FSN), or recalls for SynthoGraft.

5. Summary of clinical evaluation and post-market clinical follow-up (PMCF)

5.1 Summary of clinical data related to equivalent device, if applicable

Current clinical data available is based only on Bicon SynthoGraft. No clinical data has been used from other devices other than to support the conclusion that SynthoGraft continues to be state-of-the-art in the industry for bone augmentation.

5.2 Summary of clinical data from conducted investigations of the device before the CE-marking, if applicable

Conformity of the SynthoGraft device was initially assessed by a Notified Body in 2009 and transferred to the current Notified Body in 2014. There were no specific pre-market clinical investigations performed on the device as part of the development of devices before the initial CE-marking.

5.3 Summary of clinical data from other sources, if applicable

Clinical data exists from a variety of sources, including post-market clinical follow-up through use in doctor offices or clinics and from clinical evaluations with use recorded in clinical articles and surveys. The clinical data within the Clinical Evaluation Report utilizes data gathered from actual SynthoGraft use.

The clinical data gathered from these sources show high survival rates of SynthoGraft through high survival rates of implants placed with the device. Few, minor complications have been noted with surgery including pain and inflammation which can be expected in any surgery. In all clinical data reported there have been no instances of serious adverse events or deaths. The clinical data gathered suggested the benefits of SynthoGraft outweighed any risks as an implant was subsequently able to be placed after the healing period which will vary from patient-to-patient but is typically four to six months after placement.

From the literature review, SynthoGraft as used in the following selection of articles:

1. Evaluation of β-tricalcium phosphate in human infrabony periodontal osseous defects: a clinical study. Chawla K, Lamba AK, Faraz F, Tandon S. Quintessence Int. 2011 Apr;42(4):291-300.
2. Analysis of bone formation after sinus augmentation using β-tricalcium phosphate. Schulze-Späte U, Dietrich T, Kayal RA, Hasturk H, Dobeck J, Skobe Z, Dibart S. Compend Contin Educ Dent. 2012 May;33(5):364-8.
3. Coelho, Paulo G., et al. "Physico/chemical characterization and preliminary human histology assessment of a β-TCP particulate material for bone augmentation." Materials Science and Engineering: C 29.7 (2009): 2085-2091.
4. Daher, Shadi, et al. "Histological Analysis of an Implant Retrieved from a β-Tricalcium Phosphate Graft after 4 Years: A Case Study." Journal of Long-Term Effects of Medical Implants 29.2 (2019).
5. Urdaneta RA, Daher S, Leary J, Emanuel KM, Chuang SK. The survival of ultrashort locking-taper implants. Int J Oral Maxillofac Implants. 2012 May-Jun;27(3):644-54. PMID: 22616059.
6. Rodríguez, Valentina Rodríguez, et al. "Use of beta-tricalcium phosphate bone graft in dental implants for bone regeneration." Bionorte 11.1 (2022): 182-189.

Table 3 and Table 4 below summarize the literature included for the evaluation of the safety and performance of SynthoGraft. Clinical performance can be evidenced by the survivorship of the dental implants placed with SynthoGraft. Clinical safety can be evidenced by what complications occurred directly after and up to nine months after the placement of SynthoGraft including any complications and adverse events, and through failures of the subsequent dental implant placed at the site.

Other data from the implementation of the PMCF plan showed no changes in the likelihood of an undesirable side-effect, no significant increase in the frequency or severity of incidents, no trends, and no other main findings including serious adverse events, rejection, or misuse.

Table 3 – Literature Summary Characteristics

Reference / Author (Year)	Study Design	No. of Patients	No. of Implants (SynthoGraft)	Age Mean / Range (if known)	Intervention (related to bone grafting)	Implant Staging	Follow-up Range
1. Chawla (2011)	Prospective Study	24	12 placed w/ SynthoGraft	18 to 50 years	SynthoGraft placed with open flap debridement (OFD) and OFD alone for bone defects. Sites were protected with eugenol-free periodontal dressing.	Immediate graft placement	7 days to 6 months
2. Schulze-Späte (2012)	Prospective Study	6	6 placed w/ SynthoGraft	30 to 65 years	SynthoGraft placed for sinus floor augmentation and covered with a resorbable collagen membrane	Delayed	Up to 12 months
3. Coelho (2009)	Prospective Study	12	12 placed w/ SynthoGraft	Not specified	SynthoGraft placed for sinus floor augmentation with resorbable collagen membrane.	Immediate graft placement	Three, six, and nine months for each patient
4. Daher (2019)	Case study	1	1 w/ SynthoGraft	47	SynthoGraft, 50-500µm, placed for an internal sinus lift with 5x6mm Integra-CP implants	2-stage	4 years
5. Urdaneta (2012)	Retrospective Cohort Study	291	410, 119 placed w/ SynthoGraft	58.9	15 patients had SynthoGraft placed prior to implant placement, 104 patients had SynthoGraft placed at time of implant placement. Inlay grafting of the max sinus, onlay grafting to extend the alveolar process or combination.	Delayed and immediate bone graft and implant placement	20 months average
6. Rodríguez (2022)	Case Report	1	1 w/ SynthoGraft	43	SynthoGraft, 50-500µm, placed for alveolar bone preservation with Bicon implant, upper right canine	Immediate implant and graft placement	3 months

Table 4 – Safety and Performance Summary

Reference / Author (Year)	Study Design	# Failures	Survivorship	Adverse Events (%)	Other Outcomes	Comments
1. Chawla (2011)	Prospective Study	0	No rejection of SynthoGraft.	0 of 12 devices (0%)	Mean plaque index (PI), gingival index (GI), probing depth (PD), and clinical attachment level (CAL) values were improved statistically and significantly compared to baseline. Baseline mean PD was 9.67±2.35mm in open flap debridement (OFD)+ SynthoGraft and was 7.58±1.08 in OFD-treated sites. At 6 months, PD was 4.00±1.60mm in the OFD+SynthoGraft and was 2.67±0.65 in OFD-treated sites. There were no significant differences between the two.	While the performance of OFD+ SynthoGraft was remarkably good, no conclusion could be clearly drawn about whether it was better than OFD alone due to the number of factors involved. No complications such as allergic reactions, abscesses, or infections were observed throughout the study period. There were no rejections of SynthoGraft.
2. Schulze-Späte (2012)	Prospective Study	0	No complications or implant failures. No rejection of SynthoGraft.	0 out of 6 devices (0%)	Bone levels after augmentation were significantly higher than the baseline measurements (3.21±0.9 mm before to 13.86±1.1mm after augmentation). The number of osteoclasts around bone decreased from 2.6±1.4 per mm^2 at 21-30 weeks to 1.1±0.5 per mm^2 at 38-40 weeks.	No inflammatory responses or rejections of SynthoGraft. No complications or implant failures reported.
3. Coelho (2009)	Prospective Study	0	No rejection of SynthoGraft was found.	0 out of 12 devices (0%)	Histologic sectioning over time showed increased regions of new bone or bone organization.	Bulk and surface chemical analyses did not show any contaminants in the SynthoGraft material. The graft material was safe in that no contaminants were found and there were no reported issues prior to the planned retrievals

Reference / Author (Year)	Study Design	# Failures	Survivorship	Adverse Events (%)	Other Outcomes	Comments
4. Daher (2019)	Case study	0	SynthoGraft had integrated into the bone at the time of the explant in all four of the patient's implants.	0 out of 1 device (0%)	Variety of cell structures showed osseointegration had been successfully achieved and maintained between the implant surface and the grafting material.	The patient had a desire to have nonmetallic implants even though there were no issues with his four implants and no long-term evidence for metal-free implant use. The risk was likely greater in removing the implants than leaving them, but the patient wanted to have non-metallic implants even though they were not causing any issues. The SynthoGraft had not caused any issue and there had been successful function and osseointegration of the implants.
5. Urdaneta (2012)	Retrospective Cohort Study	0	No rejection of SynthoGraft.	1 out of 119 devices (0.84%)	In 3 cases, at implant uncovering appointments, SynthoGraft was placed due to insufficient bone at implant site (1 with pain and inflammation), all three were successfully restored with crowns and had no further noted complications. No reported rejection or failure of SynthoGraft.	15 patients had SynthoGraft placed prior to implant placement, 104 patients had SynthoGraft placed at time of implant placement.
6. Rodríguez (2022)	Case Report	0	No rejection of SynthoGraft.	0 out of 1 device (0%)	Adequate healing without the presence of gingival retraction, no bone loss observed with tomography.	Osteoconductive benefitted proliferation and regeneration of bone.

5.4 An overall summary of the clinical performance and safety

The complaint rate for SynthoGraft is low which is indicative of the performance and safety of the device. There is nothing new from the clinical literature that would indicate that SynthoGraft is not performing adequately or is unsafe. The biocompatibility risk of the materials used in SynthoGraft was determined to be low due to published literature and recognized international standards, as well as more than a decade of use.

From the Clinical Evaluation Report and PMCF data, patients are likely to see a bone defect fill without any rejection of SynthoGraft. The main goal of having a dental implant osseointegrate was achieved at 95% or greater in many of the clinical literature articles with over five years of data. There are no clinical claims in the IFU; there is mention that patients may be able to obtain a dental implant within 4-6 months of healing, but that is only a suggestion and is not concrete due to a variety of patient factors. However, from the clinical data in the CER, implants were placed and restored typically within 6 months, though some took as long as ten months depending on patient healing and factors.

The clinical performance of SynthoGraft with high survivorship and low undesirable side effects has led to benefits for the patient which include allowing the opportunity for the placement of a subsequent implant and in turn restored chewing ability for the patient.

Table 5 – Overall Performance for SynthoGraft

Performance Outcome	**Survivorship**		
	# of failures reported of SynthoGraft	**# of SynthoGraft**	**Cumulative Success Rate**
	0	151	151/151 (100%)

Table 6 – Overall Safety for SynthoGraft

Safety Outcome	**# of adverse events**	**# of SynthoGraft**	**Adverse Event Rate**
	1	151	1/151 (0.66%)

5.5 Ongoing or planned post-market clinical follow-up

Clinical evaluations will be performed to determine any new or previously unidentified risks would cause a change in the benefit/risk ratio. In addition, the evaluations will review any changes to state-of-the-art. Per the latest approved PMCF plan, surveys and literature reviews continue to be the post-market clinical follow-up method. There are currently no unanswered questions relating to the use of the device that need to be investigated. If there are any emerging risks, complications, or unexpected device failures these will feed into the risk analysis and be investigated.

6. Possible diagnostic or therapeutic alternatives

Alternatives to SynthoGraft may be other synthetic or alloplastic bone grafts made by other manufacturers available on the market, or alternatives to synthetic bone grafts are xenografts, autografts, or allografts. Any of these devices can be used to perform the required function of bone regeneration but may present other risks. Below is a tabulated summary of alternatives.

Therapeutic Alternative	Description	Benefit	Risk
Autografts	Bone harvested from an individual through a secondary surgery site	Low risk of rejection	Limited Availability Donor site morbidity/infection/pain
Allografts	Bone obtained from a compatible living donor or cadaveric bone.	Unlimited availability	Low risk of disease transmission Possible rejection
Xenografts	Grafting material derived from a genetically unrelated species such as bovine bone.	Unlimited availability Lowered resorbability Good ridge preservation	Limited clinical data / short observation periods

7. Suggested profile and training for users

The placement of SynthoGraft should only be performed by or under the supervision of trained personnel with experience with the surgical techniques associated with biomaterials including licensed medical or dental health care professionals. Bicon offers training courses on how to place Bicon implants successfully which includes the use of SynthoGraft and has an array of restorative options for learning.

8. Reference to any harmonized standards and common specifications (CS) applied

The following harmonized standards and guidance documents were applied or considered during the clinical evaluation, including input processes such as design and development and output processes such as PMCF plans and reports, of SynthoGraft. Harmonized standards relevant to other processes, such as the quality management (EN ISO 13485:2016) and risk management (EN ISO 14971:2019) systems, are addressed in the General Safety and Performance Requirements (GSPR) document (GSPR-002v03). EN ISO 14155:2020 has not been applied or considered during the clinical evaluation, as no clinical investigations have been undertaken to assess the safety or performance of SynthoGraft. All standards have been applied in full unless otherwise noted below:

Standard	**Title**
ASTM F1088 (2018)	Standard Specification for Beta-Tricalcium Phosphate for Surgical Implantation
EN 1642 (2011)	Dentistry. Medical devices for dentistry. Dental implants
EN 62366-1 (2015)	Medical devices: Part 1: Application of usability engineering to medical devices
EN ISO 10993-1 (2020)	Biological evaluation of medical devices. Evaluation and testing within a risk management process
EN ISO 11137-1 (2015)	Sterilization of health care products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
EN ISO 11607-1 (2020)	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2 (2020)	Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes
EN ISO 11737-1 (2018)	Sterilization of medical devices – Microbiological methods – Part 1: Determination of a population of microorganisms on products
EN ISO 13485 (2016)	Medical devices. Quality management systems. Requirements for regulatory purposes

Standard	Title
EN ISO 14971 (2019)	Medical devices. Application of risk management to medical devices
EN ISO 15223-1 (2021)	Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements
EN ISO 20417 (2021)	Medical devices – Information to be supplied by the manufacturer
ISTA 3A (2018)	Packaged-Products for Parcel Delivery System Shipment
MDCG 2019-9 (2022)	Summary of safety and clinical performance – A guide for manufacturers and notified bodies
MDCG 2020-6 (2020)	Regulation (EU) 2017/745: Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC or 90/385/EEC
MEDDEV 2.7/1 (2016)	Clinical Evaluation: A Guide for Manufacturers and Notified Bodies
MEDDEV 2.12-1 (2013)	Guidelines on a Medical Devices Vigilance System

9. Revision history

SSCP revision number	Date issued DD-MM-YYYY	Change description	Revision validated by the Notified Body
00	30-10-2020	Original issue	☐Yes ☒ No
01	15-04-2021	Added SRN numbers	☐Yes ☒ No
02	05-10-2022	Update standards	☐Yes ☒ No
03	21-02-2023	Update to align with CER	☐Yes ☒ No
04	19-04-2023	Add patient section	☐Yes ☒ No
05	27-06-2023	Update to align with technical documentation	☒ In progress ☐Yes Validation language: English ☐ No

A summary of the safety and clinical performance of the device, intended for patients, is given below.

Bicon SynthoGraft
Summary of Safety and Clinical Performance for the Patient

Document number: SSCP-002
Document revision: 05
Date issued: June 27, 2023

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the device. The information presented below is intended for patients or lay persons. A more extensive summary of its safety and clinical performance prepared for healthcare professionals is found in the first part of this document.

The SSCP is not meant to give general advice on the treatment of a medical condition. Please contact your doctor if you have questions about your medical condition or about the use of the device in your situation. This SSCP is not meant to replace an Implant card or the Instructions For Use to provide information on the safe use of the device.

1.0 Device identification and general information

Device trade name:	SynthoGraft®
Manufacturer information:	Name: Bicon, LLC Address: 501 Arborway Boston, MA 02130 USA
Basic UDI-DI:	081311002SYN9L
Year Device was first CE-Marked	2009

2.0 Intended use of the device

Intended purpose:	To help with bone growth.
Indications:	SynthoGraft is designed for: • The filling of bone holes, bone defects, and tooth sockets • To help provide new bone and save existing bone to place a dental implant
Intended patient groups:	Patients with missing teeth or who need of tooth replacement.
Contraindications:	SynthoGraft should not be used for patients with gum or mouth infections, uncontrolled systemic diseases, infections, thyroid or kidney disease, bleeding disorders, psychological and neurological problems, or in any other instance where the doctor believes that surgery or the use of SynthoGraft should not be used.

3.0 Device description

SynthoGraft is a dental synthetic bone graft made of pure-phase beta-tricalcium phosphate. The device is an implant that is naturally used by your own body to help make new bone. It does not need to be removed. SynthoGraft is sterilized before it is used and is only able to be used once.

3.1 Materials/Substances in contact with patient tissues

The SynthoGraft particles will only be in contact with tissues in the mouth where it is placed. The amount that is used will depend on the size of the hole or defect in the bone and number of holes to fill (number of teeth to be replaced). One vial of SynthoGraft may contain 0.25 grams (g) to 2.0 grams (g) of material.

3.2 Operating principle

SynthoGraft is made up of the same elements that are in bone. SynthoGraft may be resorbed by the body and turned into your own bone during healing, usually within 4-6 months. The purpose of SynthoGraft is for your body to have enough bone after healing so that you can have a dental implant placed. Some patients may take longer to form new bone than others.

3.3 Accessories

Dental sutures are used to close the surgery site.

4.0 Risks and warnings

Contact your healthcare professional if you believe that you are experiencing side-effects related to the device or its use or if you are concerned about risks. This document is not intended to replace a consultation with your healthcare professional if needed.

Synthetic bone grafts have been safely used in dental surgeries for over 30 years. SynthoGraft is less likely to have rejection problems as it is a synthetic however, there is still a possibility of risks and undesirable side effects. Possible complications that can happen with any dental surgery include pain, infection, inflammation, or other injury.

Residual risks and undesirable effects

- Rejection of the grafting material or allergic reaction
- Lack of osseointegration
- Bone loss
- Infection
- Inflammation, swelling or pain at the placement site
- Delayed healing

Warnings and precautions

Talk with your doctor on what to do before and after surgery. Tell your doctor immediately if any allergies and/or adverse reactions occur. As with all surgeries, caution should be taken if you have any medical conditions that may prevent surgery. Talk to your doctor if you have any of the contraindications or conditions listed in Section 2.0.

There have not been any Field Safety Corrective Actions (FSCA), Field Safety Notices (FSN), or recalls for SynthoGraft.

5.0 Summary of clinical evaluation and post-market clinical follow-up (PMCF)

SynthoGraft has been used in the dental surgical field for more than ten years in Europe and worldwide. Each year clinical evidence of the device is checked to make sure SynthoGraft is performing as it is supposed to and safely, while also checking for any new risks or side effects. The following table is a summary of the safety and performance information from the clinical evaluation of the device. The clinical evidence is based on clinical studies where SynthoGraft was used in treatment.

Device Used	Safety and Performance analysis	Potential side effect(s)
SynthoGraft	There were no reported rejections of SynthoGraft in 151 surgeries with up to four years of follow up. All patients were able to have a dental implant placed after the use of SynthoGraft and all were functional. One patient out of 151 stated they had pain and inflammation around an implant that was placed with SynthoGraft. Once uncovered the implant was found to not have enough bone. More SynthoGraft was placed in the area with no further issues, and after healing was able to have a dental implant placed.	• Rejection of the grafting material or allergic reaction • Lack of osseointegration • Bone loss • Infection • Inflammation, swelling or pain at the placement site • Delayed healing

Each year, Bicon collects additional information from scientific literature, feedback surveys and complaints to confirm the continued safety and performance of SynthoGraft.

6.0 Possible diagnostic or therapeutic alternatives

When considering alternative treatments, it is recommended to contact your healthcare professional who can take into account your individual situation.
Alternatives to SynthoGraft may be other synthetic or bone grafts made by other manufacturers, or alternatives to synthetic bone grafts are xenografts, autografts, or allografts. Any of these devices can be used to help with bone growth but may have risks.

- Autografts – Bone taken from a person through a second surgery site.
- Allografts – Bone taken from a compatible living donor or cadaver bone.
- Xenografts – Bone used from an animal such as cow bone.

7.0 Suggested training for users

Only trained, licensed medical or dental health care professionals may use the product.

8.0 Model numbers covered by this document

Catalog Number	Description	Particle Size	Grams (g) / Vial	# of Vials	Total Grams (g)
260-400-125	SynthoGraft .25g (50-500um) x5	50-500um	0.25g	5	1.25g
260-400-150	SynthoGraft 0.5g (50-500um) x5	50-500um	0.5g	5	2.5g
260-400-151	SynthoGraft 1.0g (50-500um) x5	50-500um	1.0g	5	5.0g
260-400-152	SynthoGraft 2.0g (50-500um) x5	50-500um	2.0g	5	10g
260-400-525	SynthoGraft .25g (500-1000um) x5	500-1000um	0.25g	5	1.25g
260-400-500	SynthoGraft 0.5g (500-1000um) x5	500-1000um	0.5g	5	2.5g
260-400-501	SynthoGraft 1.0g (500-1000um) x5	500-1000um	1.0g	5	5.0g
260-400-502	SynthoGraft 2.0g (500-1000um) x5	500-1000um	2.0g	5	10g