Prosthetic components instructions for use

These Instructions for Use (IFU) cover the following OsteoCare prosthetic components (together, the "**OsteoCare prosthetic components**"):

- Screw-Retained Abutments
- Direct Cast Gold Abutments
- Bridge Cast Gold Abutments
- Direct Cast Abutments
- One-Piece Ball Attachments
- Screw-Retained Ball Attachments
- PEEK Temporary Abutments
- Healing Collars
- Cover Screws
- Abutment Fastening Screws
- O-Ring Housings
- Abutment Preparation Handle

These IFU additionally cover the following OsteoCare components which are used for modelling (the "**Modelling Components**"):

- Impression Transfers
- Implant Replicas

Other OsteoCare components and instruments are covered by different instructions for use which are supplied with those components/instruments. If you have a component or instrument for which you are unable to locate the relevant instructions for use, please go to https://osteocare.uk.com/eifu/ or contact OsteoCare using the contact details provided herein. Please also refer to the Clinical Manual, which is also available at https://osteocare.uk.com/eifu/ or can requested from OsteoCare directly.

The OsteoCare prosthetic components and the Modelling Components are to be used exclusively with OsteoCare dental implants and OsteoCare reusable instruments, for the use with which they have been designed, unless otherwise stated.

(1) 	Please refer to the packaging and label of your device to identify the details (range and size) of the medical device to be used. Also to be found on the packaging and label, are provided (each beside the relevant standard symbol reproduced here for convenience) the following: (1) confirmation that the item is a medical device (*not applicable to Direct Cast Abutments, Bridge Cast Abutments, the Abutment Preparation Handle, or to Implant Replicas, since none of these is a medical device within the meaning of Regulation EU 2017/745 of the European Parliament and of the Council*); (2) lot number; (3) date of manufacture; (4) catalogue reference of the device; (5) caution (in relation to risk of aspiration of components by the patient); and (6) consult instructions for use.
(2) 	
(3) 	
(4) 	
(5) 	
(6) 	

	**The OsteoCare prosthetic components and the Modelling Components are provided non-sterile.**

Please always verify IN ADVANCE OF SURGERY that you:

- **perform adequate planning steps;**
- **have all of the correct instruments available and the correct components; and**
- **confirm instruments and components are in suitable condition for use;**
- **perform cleaning and sterilisation of OsteoCare prosthetic components, Impression Transfers, and instruments for the maintenance of hygiene standards during surgery, in accordance with the procedure described in section 4 (*Cleaning and sterilisation*) below.**

A summary of safety and clinical performance (SSCP) for Final Abutments (Screw-Retained Abutments, Direct Cast Gold Abutments, Bridge Cast Gold Abutments, One-Piece Ball Attachments, and Screw-Retained Ball Attachments) and Cover Screws and Healing Collars is available at www.osteocare.uk.com/sscp/ and on the publicly available EUDAMED database (when fully operational) or can be obtained from OsteoCare directly by request made to info@osteocare.uk.com or +44 (0) 1753 770006 or +353 (0) 212 063 393.

1. BASIC UDI-DI

The Basic UDI-DI for the above-listed components is as follows:

Basic UDI-DI	Component name	Product code
5060912952BComponentsP5	Screw-Retained Abutments	CO-SRA[Y]-[XXX]
	Direct Cast Gold Abutments	CO-BCG-[XXX]
	Bridge Cast Gold Abutments	CO-DCG-[XXX]
	Abutment Fastening Screws	CO-AFS-01[Y]
	One-Piece Ball Attachments	CO-BA[Y]OP-00[X]
	Screw-Retained Ball Attachments	CO-BA[Y]O-0[X]0
	Cover Screws	IM-COV-[XXX]
	Healing Collars	CO-HC[Y]-[XXX]
5060912952AComponentsN6	PEEK Temporary Abutments	CO-TAP[Y]-[XXX]
506091295HousingsQX	O-Ring Housings	CO-HMI-1[X]0
506091295Impression5W	Impression Transfer (closed tray/open tray)	CO-ITC-[XY]/ CO-ITO-[XY]
Not applicable	Direct Cast Abutments	CO-DCA-[XXX]
	Bridge Cast Abutments	CO-BCA-[XXX]
	Abutment Preparation Handle	IN-APH-001
	Implant Replica	CO-IRP-[XXX] CO-MIRP-[YYY]

2. PRODUCT PACKAGING

All OsteoCare prosthetic components are supplied non-sterile in a tamper-proof blister pack. If, upon receipt, the prosthetic component appears damaged, please return the same to OsteoCare for replacement.

Each package contains a single OsteoCare prosthetic component.

	**Warning: DO NOT USE an OsteoCare prosthetic component if any element of its packaging is missing, or if the packaging is damaged or has been unintentionally opened.**

3. DESCRIPTIONS AND INTENDED USE

3.1 Materials

OsteoCare prosthetic components and Modelling Components are manufactured from the following materials:

- **medical grade titanium alloy**[1]: Screw-Retained Abutments; One-Piece Ball Attachments; Screw-Retained Ball Attachments; Healing Collars; Cover Screws; Abutment Fastening Screws; Impression Transfers;
- **gold dental alloy**[2]: Direct Cast Gold Abutments; Bridge Cast Gold Abutments;
- **polyoxymethylene** (also known as acetal, POM or Delrin®): Direct Cast Gold Abutments; Bridge Cast Gold Abutments; Direct Cast Abutments;
- **polyether ether ketone** (PEEK): PEEK Temporary Abutments;
- **polycarbonate**: O-Ring Housings;
- **stainless steel 303** – Implant Replicas;
- **aluminium alloy HE30**: Abutment Preparation Handle; Mini Implant Replicas.

3.2 Intended use and clinical benefits

	**Screw-Retained Abutments** (SRA) – a component which is affixed to an emplaced two-piece OsteoCare dental implant using an Abutment Fastening Screw (AFS), with the external 2.2mm hexagon engaged with (and oriented by) the internal hex of the implant and the AFS tightened initially using a 1.5mm Hex Driver to finger tightness, and then to 30Ncm using the Torque Wrench with a Torque Wrench Connector. The SRA is available with different angulations (0 to 45 degrees, 5-degree increments) to accommodate implant angulation, and the abutment cone may be modified in the laboratory, or chair-side with a diamond or carbide bur and using the Abutment Preparation Handle. The final restoration can then be attached thereto using appropriate dental cement.
	**Direct Cast Gold Abutments** (DCGA) – a "UCLA"-type abutment (engaging) used to fabricate customised restorations, with a gold alloy base which affixes to an emplaced two-piece OsteoCare dental implant using an AFS. The 2.2mm hexagonal protrusion engages with the internal hex of the implant. The polyoxymethylene body of the DCGA is cut to size (as necessary) before waxing-up and casting-on (usually in the laboratory) using a suitable gold casting alloy. The DCGA is usually used to support single-tooth restorations. The final cast is affixed using the AFS tightened to 30Ncm using the Torque Wrench.
	**Bridge Cast Gold Abutments** (BCGA) – the same as the DCGA, except that for the gold alloy base the interface protrusion is round rather than hexagonal, so that this does not engage with the implant hex (ie, it is non-engaging). Two or more BCGAs are used together to form a cast bridge (or connected crowns), and the casting-on process ensures the correct orientation of the BCGA bases relative to each other, whereas the presence of an external hexagon in the base might prevent the positioning of the cast onto the implants. The final cast is affixed using AFSs tightened to 30Ncm using the Torque Wrench.

1 Titanium alloy 6Al-4V ELI to ASTM F-136, containing around 90% titanium, 6% aluminium and 4% vanadium.

2 A "high noble" dental alloy, containing 60% gold, 20% palladium, 19% platinum and 1% iridium.

	**Direct Cast Abutments** (DCA) – in contrast to BCGA or DCGA, this is made entirely of polyoxymethylene thermoplastic, and so is entirely burnt away during casting-on. The interface for connection to OsteoCare implants is otherwise dimensionally the same as for BCGA or DCGA, with an external hexagon for single tooth restorations (as for the DCGA) to provide an indexing and anti-rotation feature; and a "non-engaging" round protrusion for DCAs for multi-tooth restorations (as for the BCGA). The resulting cast will be affixed to the implant with an AFS.
	**One-Piece Ball Attachments** (OPBA) **–** an abutment that screws directly into an emplaced OsteoCare implant using a 2.4mm Over-Hex Driver, tightened to 30Ncm, checked using the Torque Wrench. The OPBA comprises a 2.0mm ball which retains overdentures inset with mating O-Ring Housings, and will accommodate a prosthetic angle of 0 to 15 degrees (ie, the angle between the axis of the implant and the normal to the occlusal plane);
	**Screw-Retained Ball Attachments** (SRBA) – an abutment with the same function as a OPBA, but which is affixed to an OsteoCare implant using an AFS, with the external 2.2mm hexagon engaged with (and oriented by) the internal hex of the implant and the AFS tightened initially using a 1.5mm Hex Driver to finger tightness, and then to 30Ncm using the Torque Wrench with a Torque Wrench Connector. The SRBA comprises a 2.0mm ball angled with the respect to the implant (at 20, 30 or 40 degrees) to "correct" the angle of the restoration relative to the angle of the emplaced implant.
	**Healing Collars** – a temporary abutment which is used either for a two-stage delayed-loading or one-stage delayed function protocol, and which allows the healing and contouring of peri-implant soft tissues without occlusal loading, also allowing peri-implant bone to heal undisturbed. It is affixed directly to the implant using the 1.5mm Hex Driver to finger-tightness (5-10Ncm), and can remain in position for up to six months.
	**Cover Screws** – a temporary component which is used in a two-stage surgical protocol and which affixes directly to the implant using the 1.5mm Hex Driver to finger-tightness (5-10Ncm) immediately following placement of the OsteoCare implant and prior to the surgical flap being replaced. The Cover Screw protects the inner part of the implant from ingrowth of peri-implant tissues during the healing phase, and ensures undisturbed healing of peri-implant bone. Cover Screws should ordinarily remain in place for no longer than six months. A Cover Screw is usually provided packaged with the two-piece Implant to which it is to be affixed (if required as part of a two-stage surgical protocol). As such, **it is provided already clean and sterile.** Clinicians may nevertheless request a Cover Screw to be provided separately, in which case cleaning and sterilisation must be performed in accordance with section 4 (*Cleaning and sterilisation*) below.
	**Abutment Fastening Screws** – used as indicated above to affix an OsteoCare abutment in position on an OsteoCare implant and tightened to 30Ncm using the procedure described in the Clinical Manual as the "AFS tightening procedure".

	**PEEK Temporary Abutments** – a temporary abutment which affixes to an emplaced two-piece OsteoCare dental implant using an Abutment Fastening Screw (AFS), with the external 2.2mm hexagon engaged with (and oriented by) the internal hex of the implant and the AFS tightened initially using a 1.5mm Hex Driver to finger tightness, and then to 30Ncm using the Torque Wrench with a Torque Wrench Connector, when used to anchor a provisional restoration. The PEEK Temporary Abutment is angulated (0 to 45 degrees, 5-degree increments) to accommodate implant angulation, and is designed to anchor a provisional restoration for up to 30 days, additionally allowing for an implant-level impression using the closed-tray technique.
	**O-Ring Housings** – for use with OPBA or SRBA or with Mini or Midi Ball implants, it holds a nitrile rubber O-ring and is cemented into an overdenture. The O-ring provides retention upon the ball of the OPBA or SRBA or Mini/Midi Ball implant.
	**Impression Transfers –** for use in transferring implant position to an implant-level impression (closed tray or open tray) for the preparation of cast models of the patient's jaw.
	**Implant Replicas –** once an impression has been taken of the patient's mouth using Impression Transfers, an Implant Replica allows the clinician or laboratory technician to replicate the position of the implant hexagon in the patient's mouth in the master model.
	**Abutment Preparation Handle** – preparation of SRAs (which is to say, the removal of excess material so that the prosthetic restoration can be cemented into position onto the abutment). The SRA is affixed to the Abutment Preparation Handle using a AFS and the handle is held in the hand or in a vice. A carbide or diamond bur can then be used to grind away the excess material from the cone of the SRA. This simplifies the preparation process for dental technicians in the laboratory.

4. CLEANING AND STERILISATION

OsteoCare prosthetic components are **single-use only components** which are delivered decontaminated but **non-sterile**, subject to the following sentence. Cover Screws which are packaged with Implants are supplied clean and sterile and are ready for immediate placement, therefore this section 4 does not apply. This section 4 does apply to Cover Screws which have been supplied separately.

With the exception of Implant Replicas – which are laboratory-only components – and subject to any modification operations to be performed at the laboratory and undertaken first, **all OsteoCare prosthetic components must be removed from any direct packaging, then cleaned, disinfected and sterilised before use as set out below**.

4.1 Cleaning

OsteoCare recommends that the steps set out below are performed while wearing suitable clean protective clothing and equipment, and that individual components are handled using tweezers such as the Titanium Tweezers provided in the Universal Surgical Kit or separately.

- OsteoCare prosthetic components should be removed from any direct packaging or container, then cleaned (according to the manufacturer's instructions) using CE-marked detergent and/or disinfectant (pH 5 to 9) specific to the cleaning of medical devices;
- the use of an ultrasonic bath is recommended, with immersion in detergent according to the detergent manufacturer's instructions;
- following cleaning and prior to sterilisation, OsteoCare prosthetic components should be rinsed using distilled/deionised/purified/sterile water to remove the detergent/disinfectant;
- following cleaning and rinsing, OsteoCare prosthetic components should be subjected to visual inspection to check for residual soiling.

4.2 Sterilisation

OsteoCare prosthetic components should be disassembled and then placed in a suitably-sized, sealable, porous paper autoclave pouch and sterilised using steam. We recommend a minimum temperature of 134°C for at least three minutes using a Class B autoclave. The use of a passive, gravity displacement autoclave (one without vacuum assisted air removal) is not recommended for wrapped (pouched) items. The components should be allowed to cool to room temperature.

5. INDICATIONS FOR USE

OsteoCare prosthetic components connect to two-piece OsteoCare dental implants (except O-Ring Housings, which may also be used with one-piece ball-type OsteoCare dental implants) and are designed for use for the purposes set out in section 3 (*Description and intended use*) above. They are indicated for adults for the treatment of complete or partial edentulousness in the mandible or the maxilla.

OsteoCare prosthetic components may be used in one-stage or two-stage surgical protocols for immediate, early, or delayed loading depending upon the nature of the surrounding bone and the degree of stability of the OsteoCare dental implant to which it attaches.

PEEK Temporary Abutments are for short-term use (**for no longer than 30 days in position in the patient's mouth**) for anchoring provisional restorations during healing of peri-implant tissues and/or while Final Abutments and the final restoration are being prepared.

OPBAs and SRBAs are for anchoring of implant-retained overdentures into which have been fixed (using acrylic resin) O-Ring Housings for retention of the ball design feature.

The **Abutment Preparation Handle** can be used by the clinician to modify SRAs chair-side using a diamond or carbide bur.

Impression Transfers may be used for taking impressions using closed- or open-tray indirect impression techniques, and Implant Replicas can then be used for creating the working model of the patient's jaw.

6. PLACEMENT PROCEDURES

For a detailed explanation of procedures for the placement of OsteoCare prosthetic components, please refer to the Clinical Manual.

6.1 Planning

To ensure the long term survival and success of implant surgery and subsequent restoration and to satisfy aesthetic and hygienic requirements, detailed planning is strongly recommended.

A number of factors must be taken into consideration during the planning process, including: the patient's needs and physical characteristics, the biomechanics of the proposed restoration (for example, the presence of cantilevers), the neighbouring and opposing teeth, the occlusal and articulation conditions, phonetic aspects, aesthetics (dental, gingival and facial) and, in addition, the type, size and location of the implants in the mandible and maxilla. Effective planning requires

interdisciplinary cooperation, ie, the cooperation of the dental surgeon, prosthodontist, and dental technician.

The clinician must also be aware of the position of sensitive anatomical structures in the patient's mouth to minimise the risk of damage to the same.

The clinician must ensure an appropriate loading protocol is established where undisturbed healing is preferable (for example, in bone grafting or sinus augmentation situations), ensuring that provisional restorations avoid functional loading. The clinician must also ensure that where PEEK Temporary Abutments are employed, 30 days is a sufficient period to allow healing of the relevant peri-implant tissues or graft/augmentation site – if this is not sufficient time for healing to occur, then PEEK Temporary Abutments should not be used as **they are indicated only for use for a maximum of 30 days**, and Cover Screws or Healing Collars should be used instead.

6.2 Ball attachments

Planning in relation to retention of overdentures should take into account the consensus on optimal treatment for mandibular overdentures. The standard of care according to professional consensus is the use of two-implant-supported overdentures (see **Feine et al**, *The McGill Consensus Statement on Overdentures Mandibular two-implant overdentures as first choice standard of care for edentulous patients. Gerodontology.* 19. 3-4. (2002); and **Thomason et al**, *The York consensus statement on implant-supported overdentures.* European Journal of Prosthodontic and Restorative Dentistry. 2009 Dec; 17(4):164-5). There is nevertheless some dissent from this view, including studies showing alternatives of three- or even single-implant supported mandibular overdentures.

There is no equivalent consensus on the optimum configuration for anchoring maxillary overdentures, but four or more anchor-points are suggested in the literature.

6.3 Healing

The healing period varies depending on the quality of the bone at the implantation site, the tissue response to the implanted device and the surgeon's evaluation of the patient's general health as well as the bone density at the time of the surgical procedure.

Where the clinician has performed complex surgical procedures such as bone grafts, sinus augmentation, and/or ridge augmentation procedures (including ridge splitting), longer healing periods of undisturbed healing may be required depending upon the desired surgical and healing protocol.

The patient should avoid applying excessive force to the dental implant during the healing period and the clinician should provide instructions accordingly. The clinician should also evaluate occlusion of the prosthetic restoration to avoid excessive force during healing or any force where undisturbed healing is required.

6.4 Preparation

Prior to attaching the OsteoCare prosthetic component to the implant, the clinician should thoroughly clean and rinse the inner part of the implant (which is used to affix the OsteoCare prosthetic component). The clinician should also take X-rays after the abutment is affixed to the implant to verify that it is correctly seated.

Some OsteoCare prosthetic components are small and present a risk of swallowing or aspiration. The clinician should take appropriate steps during treatment to protect patients as a means of preventing swallowing or aspiration[3].

6.5 Abutment Fastening Screw (AFS)

Screw-Retained Abutments, Direct Cast Gold Abutments, Bridge Cast Gold Abutments, Screw-Retained Ball Attachments, and PEEK Temporary Abutments (and also cast prostheses made using Direct Cast Abutments) are for use with AFSs to affix to an OsteoCare two-piece dental implant.

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[3] For practical steps, please see, eg, the discussion section of **Huh J**, Lee N, Kim K-Y, Cha J, Kim K-D, Park W. Foreign body aspiration and ingestion in dental clinic: a seven-year retrospective study. *J Dent Anesth Pain Med*. 2022 Jun;22(3):187-195.

AFS tightening

The relevant abutment should be placed onto the implant in the planned orientation, ensuring that the abutment is seated with the hexagonal interfaces of the abutment and implant fully engaged. The clinician can then screw in the Abutment Fastening Screw (AFS) (1) using a 1.5mm Hex Driver tightened to finger tightness; and (2) using the 1.5mm Torque Wrench Connector and the Torque Wrench and tightened to 30Ncm torque; or alternatively using a 1.5mm Handpiece Driver attached to a dental handpiece, provided always that the clinician is able to control the applied torque to 30Ncm (ie, that the dental handpiece has adjustable torque control). Where torque control is not available using a dental handpiece, the clinician must only use the Ratchet and Torque Wrench to perform insertion.

In all cases, the relevant component should be re-tightened and checked after 10 minutes to account for any settling at the implant-abutment interface. The insertion torque must not exceed 30Ncm. Please refer to the AFS tightening procedure in the Clinical Manual.

AFS fractures

There are very few reported instances of AFS fractures. The risk of such a fracture occurring is increased by loosening of the AFS and consequent unseating of an abutment from the relevant implant. Where a fracture occurs, please contact OsteoCare for technical advice and support using the details provided in Section 15 (*Manufacturer and EU authorised representative*) below.

6.6 One-Piece Ball Attachments

One-Piece Ball Attachments can be tightened directly using the 2.4mm Over-Hex Driver and Ratchet tightened to a torque of 30Ncm (checked using the Torque Wrench).

The relevant component should be re-tightened and checked with the Torque Wrench after 10 minutes to confirm that the torque remains 30Ncm and account for any settling/relaxation at the implant/abutment interface. Please refer to the AFS tightening procedure in the Clinical Manual.

6.7 Screw-Retained Abutments (SRAs)

SRAs are usually pre-prepared in the laboratory to the clinician's requirements for subsequent attachment of the final restoration.

SRAs may also be prepared for restoration chair-side (ie, immediately following the placement procedure in immediate loading scenarios) using an appropriate carbide or diamond bur to reduce the post to the desired shape and size for the prosthetic restoration. This should generally be performed using the Abutment Preparation Handle and therefore away from the patient's mouth, but may exceptionally be performed with the SRA in position and affixed to the implant. In the latter case, the clinician must take appropriate measures to: (1) prevent titanium alloy debris from the reduction of the post being swallowed or aspirated by the patient; (2) ensure that the Implant does not overheat and cause thermal necrosis in the peri-implant bone – by using copious irrigation and a "pecking" application of the bur to the SRA's post.

6.8 Cement retention

Where a cement is used to retain the prosthesis (whether provisional or final) to the two piece abutment, retention of the restoration can be improved by roughening the surface of the SRA – the clinician can assess with the laboratory how best to achieve this.

You must ensure that any excess cement is removed at the time of placement, in particular any cement at the level of the gum or below. This can be achieved with dental floss, curettes, or ultrasonic scalers. Subgingival cement (ie, around the gingival sulcus) can adversely affect the health of peri-implant hard and soft tissues. Removal of cement at a later date is not preferred as this may lead to damage to the peri-implant tissues.

Best practice for the use of cement should be followed to ensure controlled application of cement and thereby decrease the possibility of cement retention and associated risk of peri-implant disease.

6.9 Cover Screw and Healing Collar

A Cover Screw is usually supplied with each two-piece implant and is embedded in the top of the carrier cap with which the implant is supplied. In this situation, further cleaning and sterilisation of the Cover Screw is neither necessary nor desirable. For use in a two-stage surgical protocol, the implant

is placed and then the Cover Screw is removed from the carrier cap using a 1.5mm Hex Driver (long or short), remaining on the tip of the Hex Driver and immediately offered up to the coronal end of the emplaced implant and screwed into position.

The Cover Screw is tightened only using finger pressure on the Hex Driver (or, where adequate torque control is available such as is with some electrical dental handpieces, to between 5 and 10Ncm). The same applies to the tightening of a Healing Collar. **Do not use the Ratchet or Torque Wrench** – this can result in the Cover Screw or Healing Collar *cold-welding* to the implant, and the clinician being unable to remove it at the second stage without disturbing the osseointegration of the implant with peri-implant bone, or removing the implant altogether.

At the second stage surgery, the Cover Screw is uncovered and should be closely examined before removal to ensure that there has been no bone overgrowth during healing. If there is some bone overgrowth, a piezoelectric ultrasonic tip can be used to gently remove any bone which prevents the Cover Screw from being unscrewed.

Equally, one-stage delayed-loading protocols may employ Healing Collars for soft-tissue healing, which are inserted using a 1.5mm Hex Driver tightened using finger pressure (or to 5 to 10Ncm, provided that torque can be controlled appropriately if using a dental handpiece).

Again, do not use the Ratchet or Torque Wrench to affix a Cover Screw or Healing Collar into position.

6.10 Repeat connection/disconnection at the implant-abutment interface

Clinicians should be aware that repeated connections and disconnections at the implant-abutment interface are implicated as a factor that increases peri-implant bone loss, and should take care to minimise the number of such connections/disconnections to reduce the risk of this leading to damage to peri-implant tissues and plan patients' treatments accordingly.

7. FOLLOW-UP CARE

Patients should be instructed in appropriate oral hygiene and care of the implants and restorations. Periodic follow-up appointments should be made to confirm and maintain adequate function of the restoration and health of the surrounding tissue, and rubber O-rings for overdenture retention should be monitored for wear and replaced as necessary.

Refer also to the OsteoCare Clinical Manual, which includes a *Monitoring and maintenance* section.

8. DOCUMENTATION

OsteoCare products are identifiable by their catalogue and lot numbers.

OsteoCare strongly recommends keeping complete clinical, radiographic, and photographic documentation of all procedures performed on each patient.

9. CONTRAINDICATIONS

Clinicians should be aware of any patient allergies that may lead to difficulties and discomfort for the patient related to the OsteoCare prosthetic component, for example titanium or vanadium allergy or hypersensitivity (where a SRA, OPBA, SRBA, Healing Collar, or Cover Screw is used), and palladium or iridium allergy or hypersensitivity where a BCGA or DCGA is used. Hypersensitivity to PEEK has been reported in the literature, but is extremely rare and attribution to the material is uncertain.

The clinician must include questions on patient allergies as part of the pre-treatment protocol. In the event that a patient has a history of hypersensitivity to the above materials or indeed to other materials which are likely to contact the patient during treatment (eg, latex), the clinician must consider what steps may be taken to reduce the risk of allergic reaction or to mitigate the effects of such reaction, including whether or not treatment should proceed. In addressing this risk, the clinician should consider factors such as (but not limited to): (1) the severity of previous patient reactions; (2) the symptoms likely to be presented; (3) the period during which symptoms have previously persisted; (4) the ease with which the allergy or its symptoms can be treated; (5) whether testing is appropriate; and (6) whether any special precautions are necessary.

The clinician should continue to monitor for the possibility of allergic responses after treatment.

Please refer to the Clinical Manual for other contraindications related to assessment of the health characteristics of the patient. In particular, in the first instance the placement of a dental implant may

be contraindicated and will be a bar to the placement of an OsteoCare prosthetic component. The contraindication relevant to OsteoCare dental implants therefore apply indirectly but are equally relevant to OsteoCare prosthetic components. The Implants Instructions for Use or the Clinical Manual can be reviewed to understand applicable contraindications.

10. WARNINGS

	**OsteoCare prosthetic components are designed for single use only and are labelled as such. Re-use of products labelled as single use only may result in product contamination, patient infection and/or failure of the device to perform as intended.**
	The clinician must take appropriate steps during treatment to protect patients from the risk of swallowing or aspiration of small items such as OsteoCare prosthetic components.

10.1 General

OsteoCare prosthetic components should be placed by a qualified dental or maxillofacial surgeon with appropriate experience and/or training in the restoration of dental implants using prosthetic components. Surgery must only be performed in a suitable surgical environment.

A failure correctly to assess and plan surgical intervention and/or the associated prosthetic restoration, may result in permanent damage to patient tissues including sensitive structures such as nerves and membranes of the sinus. It is the clinician's responsibility to ensure that all surgical procedures and restorative techniques are performed according to generally accepted best practice and in accordance with instructions for use and the Clinical Manual. It is also the clinician's responsibility to ensure that he or she is familiar with the latest developments in clinical practice and that he or she has reviewed the latest version of the Clinical Manual, which is available at http://www.osteocare.uk.com/eifu and which is regularly updated.

Users of OsteoCare products must decide whether the application of the product is or is not suitable for the specific conditions. In case of doubt, the user should contact OsteoCare using the contact details provided in Section 15 (*Manufacturer and EU authorised representative*) below.

Surgery must only be performed in a suitable surgical environment and, if surgery is not required in the relevant circumstances, the placement of OsteoCare prosthetic components should nevertheless take place in a suitable hygienic environment. All surgical instruments must also be sterilised before use to ensure that OsteoCare prosthetic components remain sterile prior to placement.

All OsteoCare products should be used in accordance with the relevant instructions for use and the Clinical Manual. The use of OsteoCare products with tools or components manufactured by third parties for which they were not designed may invalidate the guarantees and other expressed or implied obligations of OsteoCare. OsteoCare cannot accept liability for any direct, indirect or other damage caused in connection with errors in professional decisions or procedures or by the improper handling or use of components.

10.2 Training

The information provided in these Instructions for Use and/or in the Clinical Manual is by itself not sufficient for a dental professional to use or place OsteoCare products if he or she has not undergone the necessary specialised training. OsteoCare strongly recommends that clinicians undergo specialised training in the placement of dental implants and associated surgical, planning, and restorative techniques. OsteoCare provides training and technical advice in the use of its system. Requests for such training/advice can be made using the contact details provided in Section 15 (*Manufacturer and EU authorised representative*) below.

All clinical staff should receive appropriate information, training and supervision in the safe handling, use, and disposal of sharps.

11. UNDESIRABLE SIDE-EFFECTS

Surgical procedures have an inherent level of risk of undesirable side-effects such as swelling, haematoma, and damage to sensitive anatomical structures. Patients may also experience inflammation of peri-implant tissues. Appropriate planning, patient assessment, the use of appropriate instruments, and adherence to best practice, will minimise the risk associated with undesirable side-effects. It is the clinician's responsibility to ensure that the patient is aware of such possible undesirable side-effects.

12. MAGNETIC RESONANCE IMAGING (MRI) SAFETY

OsteoCare dental implants, as well as Final Abutments, Healing Collars, and Cover Screws, contain non-ferrous metals (principally titanium, aluminium, and vanadium) which are paramagnetic (ie, they will only produce a magnetic field in the presence of an externally-applied magnetic field). OsteoCare prosthetic components (with the exception of PEEK Temporary Abutments, Direct Cast Abutments (which will not usually ever be placed in the mouth in any event), and O-Ring Housings (which should usually be removed prior to an MRI)) are opaque to MRI and will produce image artifacts.

MRI systems currently used for medical purposes apply a static field of 1.5 or 3.0 tesla, which will not impact the safety of patients with OsteoCare dental implants and prosthetic components. Removable dental prostheses, such as implant-retained overdentures, should be removed before imaging.

The clinician should be aware that PEEK Temporary Abutments will produce no (or only a very faint) image with conventional imaging techniques, and therefore that the position of the PEEK Temporary Abutment will not be very clear, or will not be present, in the radiographic image.

13. SERIOUS INCIDENT REPORTING

Patients and/or clinicians: in the event of a serious incident occurring which is caused by the device or a result of its use, please report the incident to OsteoCare at info@osteocare.uk.com or by telephone at +44 (0)1753 770006, providing details of the incident. The same information must be provided to the national competent authority of the patient/clinician.

14. DISPOSAL

OsteoCare prosthetic components should be disposed of in accordance with local laws and regulations for the disposal of contaminated surgical equipment. Where relevant, sharps waste must be disposed of into sharps boxes and segregated until final removal.

15. MANUFACTURER AND EU AUTHORISED REPRESENTATIVE

Manufacturer:

OsteoCare Implant System Limited
5-7 Colndale Road
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Contact details

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