Implants Instructions for Use

These Instructions for Use (IFU) cover the following OsteoCare implants (capitalised terms denote components supplied by OsteoCare):

- Classic Advanced
- Classic 2 Advanced
- Advanced
- Mini Ball
- Midi Ball
- Mini Post
- Midi Post
- Maxi Z
- Maxi Z One-Piece
- Maxi Z Flat-End
- Maxi Z Flat-End One-Piece
- Maxi Z Plus
- Maxi Z Flat-End Plus

The OsteoCare implants set out above (together, the "**Implants**") are to be used exclusively with (1) OsteoCare components and OsteoCare reusable instruments according to the instructions set out in relevant instructions for use and the Clinical Manual; and (2) a limited number of third-party dental abutments for use in digital workflows (Dynamic Abutment Solutions®) which have been designed and manufactured by Talladium España S.L., and the OT Equator® overdenture retention system marketed by Rhein 83 S.r.l.

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.

<table>
<tr><td>(1)  </td><td rowspan="5">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):
(1) confirmation that the item is a medical device;
(2) lot number;
(3) use-by date;
(4) date of manufacture; and
(5) catalogue reference of the device.</td></tr>
<tr><td>(2)  </td></tr>
<tr><td>(3)  </td></tr>
<tr><td>(4)  </td></tr>
<tr><td>(5)  </td></tr>
<tr><td>  </td><td>The Implants are provided sterile.</td></tr>
<tr><td>  </td><td>The Implants are packaged inside a single sterile barrier system, within a protective assembly to facilitate aseptic presentation to the osteotomy site.</td></tr>
</table>

Please always verify IN ADVANCE OF SURGERY that you:

- **perform adequate planning steps;**
- **have all of the correct instruments and components available (including making a visual check of an Implant and its specifications before removal from the sterile packaging);**
- **confirm instruments and components are in suitable condition for use;**
- **perform cleaning and sterilisation of OsteoCare prosthetic components, OC Reusable Instruments, and Other RIs for the maintenance of hygiene standards during surgery, in accordance with the procedures described in the relevant instructions for use for those instruments and components.**

Other OsteoCare components are covered by different instructions for use which are supplied with those components. If you have a component for which you are unable to locate the relevant instructions for use, please request this from OsteoCare directly. Please also refer to the Clinical Manual, which can be found at http://www.osteocare.uk.com/eifu or requested from OsteoCare directly.

A summary of safety and clinical performance (SSCP) for the Implants 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 covers all classes of dental implant produced by OsteoCare (ie, all of the above-listed Implants) and is **506091295ImplantsKH**

2. PRODUCT PACKAGING

All Implants are supplied in packaging in the following form:

- a plastic carrier cap ("**Carrier Cap**"), which is inserted into (for two-piece Implants) or into which is inserted (for one-piece Implants) an Implant which is held in position by the close fit of the interface between Carrier Cap and Implant;
- a clear plastic vial into which the Carrier Cap/Implant assembly is inserted;
- for two-piece Implants, an implant cover screw ("**Cover Screw**") which is screwed into the top of the Carrier Cap which is not inside the clear plastic vial (assembled together with the Carrier Cap/Implant, is referred to below as the "**Carrier Assembly**");
- a sealed, tamper-proof, pouch made of a clear plastic and Tyvek®;
- a cardboard outer carton with a clear plastic window, on the back of which is the label containing all of the relevant information including a Unique Device Identifier carrier (UDI carrier).

Each package contains only a single Implant and is sterilised by gamma irradiation.

	**Warning: DO NOT USE an Implant if any element of its packaging is missing, if the packaging is damaged or has been unintentionally opened, or if the Implant is loose inside the clear plastic vial (ie, it is no longer attached to the Carrier Cap).**
(1) 	Packages containing Implants should be stored in (1) a dry environment; (2) away from direct sunlight, to avoid degradation of the packaging.
(2) 	

3. DESCRIPTION AND INTENDED USE

Implants are manufactured from medical grade titanium in the form of titanium alloy 6Al-4V ELI (to the ASTM F-136:13 standard), containing around 90% titanium, 6% aluminium and 4% vanadium.

All Implants are provided in a Carrier Assembly which is intended to maintain the sterility of the Implant during surgery by enabling a "no-touch" application of the Implant to the osteotomy site.

3.1. Two-piece Implants

Basic design features

All two-piece Implants comprise the same basic internal hexagonal interface with the same size and tolerances to ensure compatibility with OsteoCare prosthetic components and hex drivers and connectors.

Compatibility

Carrier Assemblies for two-piece Implants always have a beige Carrier Cap, so that the 2.2mm drivers listed below are only to be used with the beige Carrier Cap. There are three ratchet-connected hex drivers, a long handled hex driver, and a hex driver for connection to a dental handpiece which may be used for driving a two-piece Implant during placement:

- Ratchet-connected 2.2mm Hex Driver (Short) – IN-RCDS-220
- Ratchet-connected 2.2mm Hex Driver – IN-RCD-220
- Ratchet-connected 2.2mm Hex Driver (Long) – IN-RCDL-220
- Long-handled Hex Driver 2.2mm – IN-LHD-220
- Bur Hand Piece Driver Hex – IN-BPD-220

Following placement, the connection between the Implant and OsteoCare prosthetic components is established using an internal thread for which a screw with the correct mating thread must be placed.

To fix an OsteoCare prosthetic component in position, the relevant screw is the Abutment Fastening Screw (AFS), although some OsteoCare prosthetic components such as the Cover Screw, One-Piece Ball Attachment (OPBA) and Healing Collar integrate the correct mating thread so that these can be affixed directly to the Implant rather than using the separate AFS.

The following classes of OsteoCare prosthetic component may be used with two-piece Implants:

For final restorations (together, "**Final Abutments**"):

- Screw-Retained Abutment (SRA) – requires AFS to affix
- Screw-Retained Ball Attachment (SRBA) – requires AFS to affix
- Direct Cast Abutment (DCA) – once cast, requires AFS to affix
- Bridge Cast Abutment (BCA) – once cast, requires AFS to affix
- Direct Cast Gold Abutment (DCGA) – requires AFS to affix
- Bridge Cast Gold Abutment (BCGA) – requires AFS to affix
- One-Piece Ball Attachment (OPBA) – affixed directly

For healing:

- Cover Screw – (supplied as part of the Carrier Assembly) affixed directly
- Healing Collar – affixed directly

And for provisional restorations:

- PEEK Temporary Abutment – requires AFS to affix

For impression taking

- Impression Transfer Open Tray – requires dedicated fastening screws
- Impression Transfer Closed Tray – requires dedicated fastening screws

For authorised third party restorations (together, "**Third Party Components**"):

- OT Equator® overdenture attachments – affixed directly
- Dynamic Ti-Base® abutments – requires dedicated third-party fastening screw which is supplied with the abutment (and relevant scan bodies)
- Dynamic Ti-Base® 3.0 multi-unit angulated abutments - requires dedicated third-party fastening screw which is supplied with the abutment

3.2. One-piece Implants

One-piece Implants integrate the abutment and therefore dispense with the need for a connection. The final restoration, whether crown, bridge, or overdenture, is affixed directly to the body of the Implant.

Compatibility

Carrier Assemblies for one-piece Implants (Maxi Z One-Piece, Midi Post and Mini/Midi Ball Implants) comprising a white Carrier Cap have a 2.4mm external hexagon, and therefore can only be inserted using the 2.4mm drivers listed below during placement:

- Ratchet-connected 2.4mm Over-Hex Driver (Short) – IN-OHDS-240
- Ratchet-connected 2.4mm Over-Hex Driver (Long) – IN-OHD-240
- Bur Hand Piece 2.4mm Over-Hex Driver – IN-BPO-240

Carrier Assemblies for one-piece Implants (Mini Post) comprising a black Carrier Cap have a 1.9mm external hexagon, and therefore can only be inserted using the using the following 1.9mm drivers during placement:

- Ratchet-connected 1.9mm Over-Hex Driver (Short) – IN-OHDS-190
- Ratchet-connected 1.9mm Over-Hex Driver (Long) – IN-OHD-190
- Bur Hand Piece 1.9mm Over-Hex Driver – IN-BPO-190

3.3. Intended use and clinical benefits

All Implants are intended for use as endosseous dental implants for permanent placement via surgical techniques into maxillary or mandibular bone and which are intended to form a direct structural, functional and biological adhesion to the living bone (ie, to osseointegrate) for the treatment of edentulousness and to restore dental functions such as chewing and biting, the prevention of jaw bone atrophy and/or restoration of bone volume in the jaw, and improved aesthetic appearance.

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

Except as otherwise stated below, all Implants are self-tapping dental implants suitable for use in one- or two-stage surgical protocols, using delayed, early, or immediate function loading protocols (provided sufficient primary stability has been achieved). Please refer to the Clinical Manual for drilling guides for implant site preparation.

Diagram	Product code	Intended use/clinical benefit
	IM-CA300-0[XX] IM-2CA[XXX]-0[YY]	**Classic Advanced, Classic 2 Advanced –** Implants with a straightforward cylindrical design and conventional “V”-shaped thread giving a high surface area for osseointegration to occur. Particularly suited to conventional (ie, delayed) loading protocols but can also be used in immediate or early loading protocols provided that: (1) appropriate diameter and length are selected (at least 3.75mm by 13mm for single-tooth restorations; at least 10mm long for multi-tooth restorations provided that loading forces are appropriate distributed); and (2) the bone quality is good enough (D1 or D2).
	IM-A[XXX]-0[YY]	**Advanced –** similar overall design to the Classic Advanced and Classic 2 Advanced, indicated only for placement immediately post-extraction.

	IM-MAXZ[XXX]-1[YY]	**Maxi Z –** tapered implants which form – rather than cut – the thread in the surrounding bone as they are inserted, and also compress the surrounding bone to enhance primary stability particularly in poor-quality bone. Implants may be placed in healed sites or, under suitable circumstances, immediately post-extraction in extraction sockets.
	IP-MAXZP[XXX]-1[YY]	**Maxi Z Plus –** almost identical to the Maxi Z and indicated in the same situations, the Maxi Z Plus is suitable for use with reduced-diameter platform Final Abutments (so-called “platform switching”) for improved aesthetics in anterior positions.
	IM-MZFE[XXX]-[YYY] IP-MZFEP[XXX]-[YYY]	**Maxi Z Flat-End, Maxi Z Flat-End Plus –** indicated for the same situations as Maxi Z and Maxi Z Plus, the flat apex of the Implants allows placement in positions proximate to sensitive anatomical structures in atrophic jaws, in particular the maxillary sinus, mandibular canal and mental foramen, since there is a reduced risk of perforation into such structures.
	IM-MAZP[XXX]-1[YY] IM-MZFP[XXX]-[YYY]	**Maxi Z One-Piece, Maxi Z Flat-End One-Piece** – suitable for placement in similar situations as the Maxi Z and Maxi Z Flat-End, provided that the required prosthetic angle is less than 15 degrees (if the required prosthetic angle is greater than 15 degrees, a two-piece Implant should be used to ensure appropriate functionality and aesthetics of the prosthetic restoration). The Maxi Z One-Piece and Maxi Z Flat-End One-Piece are suitable for use in particular for immediate placement post-extraction and should only be used where immediate loading is not contraindicated.
	IM-MBT[XXX]-[YYY]	**Mini/Midi Ball –** particularly suited to placement in the inter-foraminal region of the mandible for two-implant supported connection to O-Ring Housings cemented into overdentures. Not suited to immediate placement post-extraction.
	IM-MNP[XXX]-[YYY]	**Mini/Midi Post –** indicated for the same use as the Maxi Z One-Piece (including for immediate loading following immediate placement post-extraction), with particular benefit in thin, atrophic ridges. Note that Mini Post-Type Implants (with diameters of 2.35 or 2.8mm) will usually be too narrow for placement into fresh extraction sockets – please contact OsteoCare if need technical advice on whether it would be appropriate in a specific case.

Two-piece Implants are intended for use with Final Abutments, Healing Collars and Cover Screws, PEEK Temporary Abutments, Impression Transfers, or Third Party Components as the clinician requires, allowing greater flexibility than for one-piece Implants in terms of the restoration angles available. Please refer to the Clinical Manual for detailed instructions on restorative techniques applicable with the Implants, as well as to the Prosthetic Components Instructions for Use.

The clinician must prepare one-piece post-type Implants (which is to say, Mini/Midi Post, Maxi Z One-Piece and Maxi Z Flat-End One-Piece) for restoration *in situ* using an appropriate carbide or diamond bur to reduce the post to the desired shape and size for the prosthetic restoration. The clinician must take appropriate measures to: (1) prevent titanium alloy debris from the reduction of the Implant 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 an intermittent rather than continuous application of the bur to the Implant's post.

If placement of a one-piece Implant would result in an emergence of angle more than 15 degrees from the perpendicular to the occlusal plane, a two-piece Implant should be used with appropriate angled abutment.

Cover Screws are supplied sterile inserted into each Carrier Assembly of a two-piece Implant, for use with the Implant with which it is supplied (Cover Screws are platform diameter-specific) to protect the Implant interface and internal thread during healing in a two-stage surgical protocol.

Osteotomy Probe (IN-OSP-001) – with graduated markings, allows assessment of the osteotomy depth during implant surgery.

3.4. Indications

Implants are indicated for adults for the treatment of complete or partial edentulousness in the mandible or the maxilla. They are for anchoring prosthetic teeth to restore functions such as biting, chewing, and maxillofacial aesthetics.

Two-piece Implants 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 Implant.

With the exception of Advance Implants, two-piece Implants may be placed in extraction sockets immediately post-extraction or in healed bony sites. Advanced Implants are indicated only for placement into extraction sockets immediately post-extraction.

One-piece Implants are only indicated for one-stage surgical protocols and immediate loading. They may be placed in healed bony sites or extraction sockets immediately post-extraction, provided that the size of the Implant has been considered according to the recommendations in the literature. Note that Mini/Midi Ball-Type Implants should only be used in healed bony sites.

Mini Implants are small diameter, one-piece Implants (< 3.0mm diameter) which are intended for one-stage surgical protocols and immediate loading. Ball-type Mini Implants are for anchoring implant-retained overdentures into which have been fixed (using acrylic resin) O-Ring Housings for retention of the ball design feature.

All Implants are supplied as part of a Carrier Assembly to facilitate a "no-touch" placement technique to maintain sterility of the Implant during placement surgery. Carrier Assemblies for two-piece Implants include a Cover Screw which is indicated for use in two-stage surgical protocols to allow undisturbed healing of the peri-implant tissues and to protect the internal parts of the Implant.

Short implants

As a general rule, shorter Implants (8.0mm long or less) should only be placed in ridges with good bone quality. Success rates in the literature are generally higher in the mandible than in the maxilla, since bone quality in the maxilla is usually poorer. Where insufficient bone height is available in the maxilla, it is usually preferable to increase the available bone height/volume with sinus floor augmentation surgery, so that a longer Implant may be placed.

Where sufficient ridge width is available, wider diameter Implants are preferable to improve outcomes for shorter implants.

The clinician should take a more cautious approach to using shorter Implants where additional factors are present. In case of doubt, please contact OsteoCare using the contact details provided herewith for technical advice.

4. PLANNING AND SURGERY

4.1. Patient assessment

For detailed considerations relating to the examination of a potential patient, please refer to the Clinical Manual. The clinician must assess fitness for surgery (including medical and dental history), and the ability of implant therapy to solve the relevant clinical problem; as well as performing intraoral and extraoral examination of the potential patient.

4.2. Contraindications

Implant therapy is contraindicated for patients:

- who are medically unfit for an oral surgical procedure, such as those:
  - who suffer from serious internal medical problems;
  - who suffer bone metabolism disturbances;
  - with uncontrolled bleeding disorders or inadequate wound healing capacity;
  - in a poor general state of health;
  - with diabetes;
  - diagnosed with psychological or psychiatric disorders;
  - with a weakened immune system;
  - with uncontrollable endocrine disorders;
  - with illnesses requiring periodic use of steroids;
  - with prolonged therapy-resistant functional disorders;
- who have poor oral hygiene;
- who are taking proton pump inhibitors (PPIs) as long-term or continuous therapy;
- who smoke, or consume alcohol to excess;
- who are uncooperative or unmotivated;
- with xerostomia;
- with bruxism;
- whose maxillary and mandibular growth is incomplete;
- with inadequate bone volume, subject to the possibility of bone augmentation procedures;
- who are allergic or hypersensitive to titanium, vanadium, or aluminium.

Clinicians should be aware of any patient allergies that may lead to difficulties and discomfort for the patient, for example titanium or vanadium allergy or hypersensitivity.

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.

4.3. 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. OsteoCare recommends the use of planning, pre-operative, and post-operative checklists as a means of ensuring efficient use of a clinician's time and resources and effective execution of surgery[1].

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[1] Example checklists are provided in **Kupka JR**, Sagheb K, Al-Nawas B, Schiegnitz E. Surgical safety checklists for dental implant surgeries – a scoping review. *Clinical Oral Investigations*. (2022) 26:6469-6477.

A number of factors must be taken into consideration during the planning process, including: the patient's needs and characteristics, the biomechanics of 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 such as the mandibular canal, mental and lingual foramina, and local vasculature, to minimise the risk of damage to the same which might otherwise cause haematomas, or temporary or permanent loss of sensation. The use of study models, wax-ups, diagnostic imaging, and diagnostic templates is strongly recommended, as a means of ensuring that both patient and clinician understand the positioning and procedures to be performed and to facilitate discussion and allow amendments to be made.

Immediate placement of Implants post-extraction is an advanced surgical technique for which training is available from OsteoCare. The clinician should refer to practitioner texts and the latest literature on immediate loading to ensure that the correct techniques are being followed, and that potential issues and complications, such as in relation to appropriate Implant size, positioning, and interproximal bone distance, are fully considered – in particular where conflicting recommendations exist.

4.4. Preparation

Implants are **single-use only** components which are delivered sterile in the form described in Section 2 (*Product packaging*) above. Before surgery for the placement of one or more Implants, all surgical instruments (including drivers and connectors) must be cleaned and sterilised to ensure that Implants remain sterile prior to placement. Cleaning procedures for reusable surgical instruments are described in the **Reusable Instruments Instructions for Use** which is available at www.osteocare.uk.com/eifu. Surgical kits containing all of the necessary instruments are available from OsteoCare (the Universal Surgical Kit, and the Surgical Kit).

To reduce the risk of overheating peri-implant bone (which can lead to bone necrosis), the clinician should verify the condition of drills following the cleaning and sterilisation procedures and in advance of surgery.

4.5. Surgery

Surgery should only take place in an appropriate surgical setting and in which the clinician wears appropriate hygienic attire to maintain the sterility of the Implant and reusable surgical instruments.

Implants are small and present a risk of swallowing or aspiration. The clinician should take appropriate protection into account as a means of preventing swallowing or aspiration[2].

The osteotomy should be prepared according to the drilling guides provided in the Clinical Manual and using copious irrigation (with cooled physiological saline), taking into account the Implant's platform diameter and whether or not a gingival flap will be raised. The clinician must ensure that the osteotomy is prepared to a sufficient depth for the Implant, drilling to the full length of the Implant in healed sites, and 2 to 5mm beyond the apex of an extraction socket, ensuring always adequate bone volume and the safety of sensitive/delicate anatomical structures by appropriate diagnostic technique.

4.6. Implant placement

The clinician removes the vial from the Carrier Assembly, taking care not to touch the Implant. The clinician can the use Carrier Cap to position and drive (ie, screwing in) the Implant into the osteotomy to finger tightness, whereupon a driver can be used.

The Implant may be further inserted using the Ratchet connected to one of the above-listed Ratchet-connected Hex or Over-Hex Drivers, checking that the insertion torque exceeds 30Ncm by replacing the Ratchet with the Torque Wrench to verify. Alternatively, a Bur Handpiece Hex or Over-Hex Driver can be connected to a dental handpiece set to very low speed for controlled insertion of the Implant. For Implants placed in healed sites, the Implant platform should be flush with the level of the crestal

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2 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.

bone; for Implants placed in extraction sockets immediately post-extraction, the Implant platform should be 2mm below the level of the crestal bone.

Following placement, the clinician should ensure that no surgical debris has entered the inner part of the Implant (for two-piece Implants). In two-stage surgical protocols, the Cover Screw should be removed from the Carrier Cap with a 1.5mm driver (1.5mm Long Handle Driver, Bur Handpiece 1.5mm Hex Driver, Ratchet-connected Hand 1.5mm Hex Driver, or Short Hand 1.5mm Hex Driver), and inserted into the Implant using the driver to finger tightness (or 5-10Ncm, checked using an adjustable torque wrench where available). Check that the Cover Screw is properly seated and replace and suture the gingival flap to allow submerged, undisturbed healing.

If uncovering the Cover Screw reveals bone growth over the Cover Screw, any such bone should be removed very carefully using a piezo-electric tip to excise the excess bone so that the restoration will seat on the Implant without trapping any debris inside the Implant or between the Implant and prosthetic component.

4.7. 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.

Primary stability of the Implant should be verified prior to placement of the prosthesis with suitable equipment such as Periotest® M, or a resonance frequency analysis device. Excessive force applied to the Implant should be avoided during the healing period and, in the absence of primary stability, the clinician may choose to avoid placing a prosthesis altogether to allow the peri-implant tissues to heal and gain stability by osseointegration. Proper occlusion should be evaluated on the prosthetic restoration to avoid excessive force.

4.8. Restoration

Please refer to the Prosthetic Components Instructions for Use and the Clinical Manual for instructions on the placement of OsteoCare prosthetic components on an emplaced Implant.

At the time of placement of the final restoration, the clinician should ensure correct seating of the relevant abutment and the tightening of the AFS to a torque of 30Ncm in accordance with the AFS tightening procedure described in the Clinical Manual. This will reduce the risk of mechanical failure that would arise (for Implant, AFS, and/or abutment) as a result of a loosened AFS.

5. FOLLOW-UP CARE

The clinician should advise the patient of an appropriate dental hygiene regime coupled with regular follow-ups to verify that peri-implant tissues remain healthy, and to confirm and maintain adequate function of the restoration and health of the surrounding tissue so as to reduce the risk of complications which could impact long-term survival.

Refer to the *General Precautions* and the *Monitoring and maintenance* sections of the Clinical Manual.

6. 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.

7. WARNINGS

	**OsteoCare Implants 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.**

	**OsteoCare Implants are not to be resterilised.**
	The clinician must take appropriate steps during treatment to protect patients from the risk of swallowing or aspiration of small items such as Implants.

7.1. General

OsteoCare implants should only be used by a qualified dental or maxillofacial surgeon with appropriate experience and/or training in the placement and use of dental implants. Surgery must only be performed in a suitable surgical environment.

A failure correctly to assess and plan surgical intervention, including where performing advanced surgical techniques such as sinus lifts or alveolar ridge expansion and bone grafts, 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 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 www.osteocare.uk.com/eifu and which is regularly updated.

A 100% survival or success rate for implant placement cannot be guaranteed, and implant placement may lead to mechanical or clinical failure of the implant as well as to loss of peri-implant bone.

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.

Optimal results are achieved using OsteoCare products 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.

7.2. Training

The information provided in these Instructions for Use and/or in the Clinical Manual is by itself not sufficient for a qualified dental professional to use or place Implants 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 12 (*Manufacturer and EU authorised representative*) hereto.

8. 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.

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 the mandibular nerve 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 www.osteocare.uk.com/eifu and which is regularly updated.

9. MAGNETIC RESONANCE IMAGING (MRI) SAFETY

The Implants 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). The Implants and any affixed Final Abutments or Healing Abutments 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 Implants. Removable dental prostheses, such as implant-retained overdentures, should be removed before imaging.

10. 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.

11. DISPOSAL

Implants which have been removed, for which sterility is compromised, or for which the expiry date has passed, should be disposed of in accordance with local laws and regulations for the safe disposal of contaminated surgical equipment.

12. MANUFACTURER AND EU AUTHORISED REPRESENTATIVE

	Manufacturer: OsteoCare Implant System Limited 5-7 Colndale Road Poyle Industrial Estate Colnbrook Slough Berkshire SL3 0HQ United Kingdom Contact details Telephone: +44 (0)1753 770006 Fax: +44 (0)1753 770009 Sales: +44 (0)800 281 981 Email: Info@osteocare.uk.com
EC REP	*EU authorised representative:* OsteoCare Implant System Ireland Limited Lee View House 13 South Terrace Cork T12 T0CT Republic of Ireland Contact details Telephone: +353 (0) 21 206 3393 Email: Info@osteocare.uk.com

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