SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

OsteoCare dental implants – Medical device class IIb

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 SSCP is not intended to replace the Instructions For Use 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.

The following information is intended for users/healthcare professionals.

1. MANUFACTURER AND DEVICE DETAILS

1.1 Device

OsteoCare dental implants comprise the following ranges and sub-ranges (together, the "Implants"):

Table 1

Range	Reference	Catalogue reference
Classic	Classic Advanced Implant Classic 2 Advanced Implant	IM-CA300-01[Y] IM-2CA[XXX]-0[YY]
Advanced	Advanced Implant	IM-A[XXX]-0[YY]
Mini	Mini Ball Implant Midi Ball Implant Mini Post Implant Midi Post Implant	IM-MBT[XXX]-1[YY] IM-MNP[XXX]-1[YY]
Maxi Z	Maxi Z Two-Piece Implant Maxi Z One-Piece Implant	IM-MAXZ[XXX]-1[YY] IM-MAZP[XXX]-1[YY]
Maxi Z Flat-End	Maxi Z Flat-End Two-Piece Implant Maxi Z Flat-End One-Piece Implant	IM-MZFE[XXX]-[YYY] IM-MZFP[XXX]-1[YY]
Maxi Z Plus	Maxi Z Plus Implant Maxi Z Flat-End Plus Implant	IP-MAXZP[XXX]-1[YY] IP-MZFEP[XXX]-[YYY]

The Implants are part of the OsteoCare dental implant system (the "System"), which includes components and instruments designed for use specifically with the Implants.

1.2 Manufacturer details

(with responsibility for the design, manufacture and packaging of all Implants according to the Medical Devices Regulation (Regulation 2017/745 of the European Parliament and the Council) (the "Regulation"))

OsteoCare Implant System Limited ("OsteoCare")
5-7 Colndale Road
Poyle Industrial Estate
Colnbrook
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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

1.3 OsteoCare SRN: **GB-MF-000016843**

1.4 Basic UDI-DI[1]: **506091295ImplantsKH**

1.5 P01020101 – dental implants.

1.6 The Implants are **class IIb medical devices** according to Annex VIII, paragraph 5.4 (Rule 8) of the Regulation.

1.7 OsteoCare's first CE certificate covering the Implants was issued on 7 September 1998.

1.8 **Authorised representative (EC rep) details:**

OsteoCare Implant System Ireland Limited ("OIS Ireland")
Lee View House
13 South Terrace
Cork T12 T0CT
Republic of Ireland

Contact details

Telephone: +44 (0)1753 770006

OIS Ireland SRN: **IE-AR-000009841**

1.9 Notified body: **Intertek Semko AB** (single identification number = 0413).

2. INTENDED PURPOSE OF THE DEVICE, INDICATIONS, CONTRINDICATIONS, AND TARGET POPULATIONS

Intended users

2.1 The Implants are intended for placement by a qualified dental or maxillofacial surgeon with appropriate experience and/or training in the placement and restoration of dental implants.

Intended purpose

2.2 The Implants are endosseous, root-form dental implants which are intended for long-term 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, *osseointegration*).

The Implants – alone (if one-piece implants) or in combination with other OsteoCare components (if two-piece implants) – thereby provide an anchor in the bone, and scaffold above the bone, upon which a prosthetic restoration can be built and/or retained. The Implant effectively acts as an artificial analogue of the root of a natural tooth.

Two-piece Implants are designed for use with other OsteoCare components, connecting to such other components via a 45-degree conical interface with a hexagonal hole (commonly referred to as the *internal hex*) which provides orientation and anti-rotation functionality to the component (an *abutment*) affixed thereto. The prosthetic restoration is built upon the abutment.

One-piece Implants are designed for use on their own as a means of providing both anchorage in the bone and scaffold upon which the prosthetic restoration is built.

Indications

[1] Pursuant to MDCG 2019-5, the Implants are "legacy devices", since they remain on the market by virtue of Article 120(3) of the Regulation. OsteoCare has assigned a Basic UDI-DI to Implants as a common group with the same function and similar design features, and each Implant (ie, with individual range, type, diameter, length) has been assigned a UDI-DI. Nevertheless, registration in EUDAMED of the Implants has resulted in each Implant being assigned a separate EUDAMED DI pursuant to MDCG 2019-5.

2.3 Implants are indicated for surgical placement in 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 (other than Advanced 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. They 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 functional loading. They may be placed in healed bony sites or extraction sockets immediately post-extraction, provided that the diameter 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 functional loading. Ball-type Mini Implants are for anchoring implant-retained overdentures into which have been cemented O-Ring Housings for retention of the overdenture via 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.

Contraindications

2.4 Implant placement is contraindicated for patients:

2.4.1 who are medically unfit for an oral surgical procedure, such as those:

(A) who suffer from serious internal medical problems;

(B) who suffer bone metabolism disturbances;

(C) with uncontrolled bleeding disorders or inadequate wound healing capacity;

(D) in a poor general state of health;

(E) with diabetes;

(F) diagnosed with psychological or psychiatric disorders;

(G) with a weakened immune system;

(H) with uncontrollable endocrine disorders;

(I) with illnesses requiring periodic use of steroids;

(J) with prolonged therapy-resistant functional disorders;

2.4.2 who have poor oral hygiene;

2.4.3 who smoke, or consume alcohol to excess;

2.4.4 who are uncooperative or unmotivated;

2.4.5 with xerostomia;

2.4.6 with bruxism;

2.4.7 whose maxillary and mandibular growth is incomplete;

2.4.8 with inadequate bone volume, subject to the possibility of bone augmentation procedures;

2.4.9 who are allergic to or hypersensitive to titanium, vanadium, or aluminium.

3.

DEVICE DESCRIPTION

3.1 Detailed description

3.1.1 Cylindrical, screw-type dental implants made of titanium have been used for the treatment of partial or complete edentulousness since at least the late 1960s.

3.1.2 The Implants are cylindrical (Advanced, Classic Advanced, or Classic 2 Advanced), screw-type dental implants; or *root-form* (ie, tapered to mimic the form of the root of a natural tooth), screw-type dental implants (Mini, Midi, Maxi Z, Maxi Z Flat-End, Maxi Z Plus). See Section 1.1 above for details of the ranges and catalogue references for each of the Implants.

3.1.3 The Implants are made from titanium alloy 6Al-4V which contains approximately 90% titanium, 6% aluminium and 4% vanadium, plus trace elements, to the ASTM F-136:13[2] standard, with very low oxygen and iron content (so-called *extra low interstitial* or ELI). This is a material which is commonly used in surgical implant applications and which is significantly stronger and more wear-resistant than commercially pure titanium.

3.1.4 The surface of the external screw part of the Implants is treated by grit-blasting and acid-etching. This improves the qualities of the Implant surface to facilitate the process of adhesion of living bone to the material (osseointegration).

3.1.5 Before placement, a hole is made in the bone at the desired position and to the desired size, depth, and angle (often referred to as an *osteotomy*). The root-form shape of the Mini/Midi, and Maxi Z (including the Flat-End and Plus) results in enhanced mechanical stability of the Implant as it is screwed into the bone as the peri-implant bone is gently compressed. Mechanical stability achieved immediately upon implant placement is generally referred to as *primary stability*.

3.1.6 The peri-implant bone remodels around the Implant during the early stages of healing, at which time *primary* stability decreases. As bone remodelling and growth occurs, increased mechanical stability results from the biological process of osseointegration, which provides *secondary stability* – which is essential to the long-term success of the Implant.

3.1.7 Physical design of the Implant, and therefore factors such as the shape, degree of taper, thread geometry, and length and diameter, are important to *primary* stability; surface features and material (and the degree of primary stability achieved during placement surgery), as well as the surface area over which osseointegration can occur, are important to *secondary* stability.

3.1.8 Two-piece Implants have an interface that enables connection of the Implant to other components of the System. All of the Implants are compatible with one or more instruments of the System which are used to drive the Implant into position in the jaw bone. Appendix 1 (*Compatibility*) to this summary sets out the compatibility of the Implants with the different components and instruments of the System and with approved third party suppliers.

3.2 Development of ranges

OsteoCare has marketed dental implants and associated components since [1999]. The first dental implants produced and marketed by OsteoCare were the Classic Implant, which was a conventional cylindrical screw-type implant with cutaways at the apex of the Implant to allow self-tapping.

The Classic range was originally designed prior to 1992 by a company of which OsteoCare is a successor-in-title in respect of the design. The same platform sizes and precisely the same basic implant-abutment interface (for two-piece implants and corresponding

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[2] Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications

abutments) is present in currently-marketed Implants as were first marketed by OsteoCare in 1998.

The Classic Advanced, Advanced and Classic 2 Advanced are each very closely based upon the Classic design, but comprise a modified surface (grit-blasted and acid-etched) to increase the surface area for bone-to-implant contact and the rate at which osseointegration occurs; and, for the Advanced range, a flared neck with microgrooves to improve the retention and mechanical stability of the Implant in the cortical bone of an extraction socket.

Mini Implants are a design of one-piece dental implant with a small diameter (usually considered <3.0mm, although there is no fixed definition in the literature) intended for fast and cost-effective treatment where limited space and/or bone volume is available. The Mini/Midi Implant was added to OsteoCare's range in 2004, and is based upon mini dental implant designs readily available on the market at the time.

Midi Implants are one-piece Implants which are part of the Mini Implant range, but with larger diameters for clinical situations in which there is greater bone volume available.

Maxi Z Implants sit between the "Classic" implant design and the Midi Implant design, as one- or two-piece larger diameter dental implants, for which the two-piece Implants provide for angulated abutments for more flexible prosthetic restoration solutions. This enables Implants to be placed at non-ideal angles to account for awkward clinical situations such as where the Implant is placed adjacent to sensitive anatomical areas, with the angulated abutment able to provide angular correction for the prosthetic restoration. The implant-abutment interface is the same as that for the "Classic" ranges, meaning that the same abutments can be used across OsteoCare's two-piece Implant ranges.

Maxi Z Implants are also available with a flat rather than pointed apex (the "Flat-End" range) to provide greater security when placing adjacent to sensitive anatomical areas. For the same reason, Maxi Z Flat-End Implants are also available in shorter lengths (the shortest at 6.5mm), which can therefore be placed in atrophic ridges in particular in posterior errors of the mandible or maxilla.

The Maxi Z "Plus" range facilitates use of a smaller diameter abutment with a larger diameter Implant (so-called *platform switching*) by incorporating a bevelled outer coronal diameter which is designed to improve the geometry at the outer surfaces of the implant-abutment interface.

3.3 Accessories

The Implants are intended for use with instruments and components of the System or with authorised third party restorative components and associated instruments (see Section 4 (*Third party components/instruments for use with two-piece Implants*) of Appendix 1).

3.4 Compatible devices/instruments

Appendix 1 (*Compatibility*) lists other devices and products of the System intended to be used in combination with the Implants. This excludes generic devices which will be used (mostly indirectly) with Implants, such as dental handpieces or generic surgical equipment such as scalpels.

4. RESIDUAL RISKS AND UNDESIRABLE EFFECTS, WARNINGS AND PRECAUTIONS

4.1 Residual risks and undesirable effects (Table 2)

Residual risk	Comment
General surgical risks, including swelling, haematoma, and damage to sensitive anatomical structures.	Any surgical procedure carries with it an inherent level of risk: there may be known patient conditions for which the clinician considers the benefit to be worth taking the risk; there may be unknown patient conditions for which, in spite of adequate patient assessment, the clinician must adapt at the time of surgery. The risk of such issues occurring can be reduced with adequate preparation and planning, in particular with reference to pre-surgical radiographs and models and consultation with the patient. Regardless of the *surgical* skills of the clinician, there is the separate issue of the competence of the clinician to adequately plan cases which is addressed below. There are varying degrees of skill and competence for clinicians. If a clinician is qualified and is able to prove this, he or she is *prima facie* able to perform the clinical procedures to place an Implant and restore it (in appropriate environs). It is possible that clinicians will perform procedures which they are either not competent to perform (eg, because they have not previously done so or have not undertaken the necessary preparation to do so), or that they commit errors while doing so.
Inadequate treatment planning	Inadequate planning by the clinician may lead to significant problems for the patient as well as implant failure. This may result from, *inter alia*, attempt to perform a procedure for which the clinician has no training or experience, a failure of communication with the patient, or mistakes in the review of radiographs, etc, and can lead to: • insufficient number of Implants placed to support the biomechanical loads of the prosthesis in function; • undesirable positioning of one or more Implants so that the Implants directly affect sensitive anatomical features, or are unable to support the biomechanical loads of the prosthesis in function, in particular resulting in cantilevers; • the placement of Implants which are not suitable for the situation, for example because the Implant is too small to support the planned prosthesis.
Damage to peri-implant bone during osteotomy preparation may result in the failure of an Implant to osseointegrate, leading to early failure.	Osteotomy preparation at the implant site should be performed in accordance with the Burs Instructions for Use to minimise the risk of damage to the peri-implant bone, in particular through thermal necrosis.
Peri-implant tissues may have an inflammatory reaction in the presence of an Implant and/or prosthetic restoration. This may result in delayed healing, infection and inflammation and, in more serious cases, the loss of peri-implant bone, dehiscence, and early failure of the Implant.	The Implants are made from titanium alloy 6Al-4V ELI, which is widely used in surgical and implant applications because of its known biocompatibility and long history of safe use, as well as favourable physical and chemical attributes including resistance to corrosion. "*No known surgical implant material has ever been shown to be completely free from adverse reactions in the human body. Long-term clinical experience of the use of the material referred to in this specification, however, has shown that an acceptable level of biological response can be expected, if the material is used in appropriate applications*"[3].
Hypersensitivity to an Implant may result in implant failure.	There is currently no clinically reliable patch test for hypersensitivity to or allergy to titanium, and the relatively few suspected cases of titanium allergy may at least in part be attributable to hypersensitivity to nickel which is present in trace amounts in the material.
The Abutment Fastening Screw (AFS) loosens, which may result in mechanical failure including the possible fracture of the abutment or	The AFS Tightening Procedure is designed to reduce the risk of loosening of the AFS, and clinicians must comply with the AFS Tightening to ensure that the retention torque of 30Ncm is achieved after any settling has occurred. There are very few reports of AFS loosening. Nevertheless, chewing food naturally

[3] ASTM F136:13 (Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)) – Appendix X2.2

Implant.	results in the application of a rotary force to a restoration which may, in the long term, result in screw loosening. Further, screw loosening may occur where an abutment is not seated properly, so that clinicians should always ensure that post-restoration radiographs are used to verify correct seating of the abutment.
Implants are re-used	Implants are for **single use only**. Placement of an Implant which has already come into contact with another patient's tissues amounts to deliberate misuse and can lead to microbial contamination and/or cross-infection. Any clinician should be aware of the dangers of contamination and/or infection inherent from the re-use of an Implant contrary to the multiple warnings in the Implants Instructions for Use and the Clinical Manual.
The use of non-System components and/or instruments.	The use of non-System components and instruments (other than as set out in section 4 (*Third party components/instruments for use with two-piece Implants*) of Appendix 1 to this summary) may result in failure of Implants and associated components to act as intended.
Inadequate maintenance and monitoring	Problems may arise and worsen which could be dealt with quickly and easily if diagnosed early enough. The associated risk can be reduced with adequate follow-up procedures, which would therefore reduce the risk of longer-term failures as referred to in the entries immediately below.
Long-term mechanical failure	Implants are also designed to withstand high loads and are made from titanium alloy 6Al-4V ELI, which has favourable physical attributes including significantly higher strength than commercially pure titanium. Nevertheless, particularly in cases of bruxism, the restoration unit may eventually fail due to material fatigue, whether of the Implant or (more likely) the AFS and/or abutment. The risk may be alleviated by the design of the prosthesis. In circumstances of AFS mechanical failure where the Implant has retained structural integrity, universal screw removal kits are available (including short-term lending from OsteoCare) to remove the parts of the AFS which remain in the Implant and cannot otherwise be removed.
Long-term clinical failure	Complications leading to loss of an Implant may occur in the long term, and are affected by diverse factors. One of the most common causes of long term failure is peri-implantitis, but any of the contraindications noted in section 2.4 (*Contraindications*) above may contribute to long-term clinical failure. The long-term survival rate of Implants according to a retrospective study based upon 130 Implants placed in a "normal" patient population is 96.1% after five to 10 years, with a success rate (according to the ICOI Implant Quality Scale[4]) of 93.1%. This is comparable to many other dental implant systems.

4.2 Warnings and precautions

The information provided in the Clinical Manual and/or Instructions for Use 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 and 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 the Clinical Manual, Instructions for Use, or on the OsteoCare website.

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.

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

[4] See, eg, **Misch CE**, *Contemporary Implant Dentistry*, 2008 (third edition).

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 versions of the Implants Instructions for Use and Clinical Manual, which are available at www.osteocare.uk.com/eifu and which are 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 herewith.

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.

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.

4.3 Other

No field safety corrective action (FSCA) or field safety notice (FSN) has been issued in respect of any OsteoCare product.

5. SUMMARY OF CLINICAL EVALUATION AND POST-MARKET CLINICAL FOLLOW-UP (PMCF)

5.1 Summary of clinical data related to equivalent device

Very similar design concepts are used by multiple dental implant systems. In addition to reviewing its own clinical data, OsteoCare has evaluated the clinical data of a number of implants which share multiple key features with the Implants and which show substantive biological, clinical, and technical similarities to the Implants.

None of the devices so evaluated evinces any areas for concern relating to features of the substantively similar Implant. OsteoCare notes a series of studies performed in relation to a particular one-piece implant for which there was a concern around higher than expected peri-implant bone loss and related implant failures. Subsequent clinical studies showed significantly higher survival rates for the same implant, which was nevertheless removed from the market.

The most similar device produced by OsteoCare is the Maxi Z One-Piece. The Maxi Z One-Piece has been marketed by OsteoCare since 2006 and there are no reports of unexpectedly high peri-implant bone loss or implant failures.

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

A prospective clinical study conducted with the "Classic" range of Implants[5, 6, 7] with 370 consecutively placed implants showed an overall success rate of 98.6% after five years, where the implants were restored with angulated abutments ranging from 0 to 45 degrees.

5.3 Summary of clinical data from other sources

A list of clinical studies performed on the Implants, including relevant literature references, is provided in Appendix 2 hereto.

5.4 Overall summary of the clinical performance and safety

Each range of Implants described in Table 1 above is supported by clinical evidence showing adequate clinical performance, with survival and/or success rates comparable to other dental implant systems, even in compromised clinical scenarios.

OsteoCare receives very few complaints in relation to any of its products, including the Implants, which provides a very good indicator of the overall safety and efficaciousness of the Implants. Implant failures are nevertheless to be expected, since no dental implant system can show a 100% survival or success rate, in particular as time passes and patient conditions may adversely affect the integrity of peri-implant tissues.

The Implants are suitable for the treatment of partial or complete edentulousness, including – with appropriate treatment planning – in compromised situations such as in atrophic jaws. The Implants are also suitable for different surgical scenarios (two-stage, one-stage, or in fresh extraction sockets) and different loading scenarios (immediate, early, or delayed loading), subject to the clinical limitations. With suitable restorations – whether fixed or removable dental prostheses – the benefits to the patient include restoration of functions associated with natural teeth such as chewing and biting, the prevention of jaw bone atrophy and/or restoration of bone volume in the jaw, as well as improved aesthetic appearance and even speech[8].

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5 Sethi A, Harding S, Sochor P. *Initial results of the Osteo Ti implant system in general dental practice.* Eur J Prosthodont Restor Dent. 1996 Mar;4(1):21-8.

6 Sethi A, Sochor P. *Predicting Esthetics in Implant Dentistry Using Multiplanar Angulation: A Technical Note,* Int J Oral Maxillofac Implants 1995; 10; 485-490.

7 Sethi A, Kaus T, Sochor P. *The use of Angulated Abutments in Implant Dentistry: Five-Year Clinical Results of an Ongoing Prospective Study*. Int J Oral Maxillofac Implants 2000; 15:801-810

The residual risks associated with the Implants are set out in Table 2 (Section 4.1) above, and it is noted and repeated that there is a risk associated with any surgical procedure. OsteoCare nevertheless considers that these risks are significantly outweighed by the potential benefits of the treatment of partial or complete edentulousness highlighted immediately above.

5.5 Ongoing or planned post-market clinical follow-up

Post-market surveillance is ongoing and currently shows a 96.1% survival rate for the Maxi Z range of Implants (comprising Maxi Z, Maxi Z One-Piece, and Maxi Z Flat-End Implants) in "real-world" clinical practice (ie, outside of any idealised conditions associated with clinical studies where patients are likely to be selected due to their healthy status).

6. POSSIBLE THERAPEUTIC ALTERNATIVES

Prosthetic teeth may alternatively be provided by partial or complete removable dentures which are not retained by dental implants. In the absence of implants, complete removable dentures are usually retained via a seal between the lining of the denture and the mucosa; partial removable dentures may be retained by means of anchoring to adjacent natural dentition (eg, using a clasp). Particularly in circumstances where there is atrophy of the relevant jaw bone, the denture may need to be regularly relined, and/or clasps adjusted, in order to ensure that the denture is retained. Where dentures fit poorly, this can lead to ulceration and other painful side-effects. Implant-retained overdentures are much less likely to suffer from such adverse effects, particularly for complete dentures.

Other prosthetic alternatives include anchoring fixed dental prostheses to a damaged tooth or to adjacent teeth (ie, crowns and bridges), although where this is for the purpose of restoring a missing tooth, an implant-supported restoration has the advantage of bone maintenance, which is not the case for a bridge.

Alternative dental implant types also exist (as compared to endosseous implants), although such implant types are now usually only available for custom treatment and their use has become very limited due to the surgical and procedural complexity compared to cylindrical or root-form screw-type endosseous implants.

Generally available (ie, off-the-shelf) dental implants may also be made from alternative materials, most commonly commercially pure titanium or zirconia (ie, zirconium dioxide). Along with titanium alloy 6Al-4V, these materials represent the standard of care for dental implants.

7. SUGGESTED PROFILE AND TRAINING FOR USERS

Dental implants cannot be placed without prior training in the relevant surgical and restorative techniques. OsteoCare will not supply dental implants to persons who are unable to show that they have received recent accredited training in such techniques.

OsteoCare offers training courses for the placement of dental implants and associated restorative techniques. The courses are aimed at different levels of expertise, including for dentists or maxillofacial surgeons who have not previously placed dental implants, as well as for advanced techniques such as sinus floor elevation, guided bone regeneration, atrophic ridge splitting, etc. for experienced implantologists.

8. REFERENCES TO HARMONISED STANDARDS AND COMMON SPECIFICATIONS APPLIED

Standard	Date	Title
ASTM F136	2013	Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS

[8] See, eg, page 2 of Chapter 1 (*Rationale for dental implants*), Misch's Contemporary Implant Dentistry (4th Edition, Elsevier) (Resnick RR and Misch CE)

		R56401)
BS EN ISO 1642	2011	Dentistry — Medical devices for dentistry — Dental implants
BS EN ISO 7405	2018	Evaluation of biocompatibility of medical devices used in dentistry
BS EN ISO 10451	2010	Dentistry – contents of technical file for dental implant systems
BS EN ISO 10993-1	2020	Biological evaluation of medical devices – evaluation and testing within a risk management process
BS EN ISO 10993-5	2009	Biological evaluation of medical devices – tests for *in vitro* cytotoxicity
ISO 10993-9	2009	Biological evaluation of medical devices – framework for identification and quantification of potential degradation products
BS EN ISO 10993-15	2009	Biological evaluation of medical devices – identification and quantification of degradation products from metals and alloys
BS EN ISO 10993-17	2009	Biological evaluation of medical devices – Establishment of allowable limits for leachable substances
BS EN ISO 10993-18	2020	Biological evaluation of medical devices – Chemical characterization of medical device materials within a risk management process
BS 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
BS EN ISO 11137-2	2015	Sterilization of health care products — Radiation Part 2: Establishing the sterilization dose
BS EN ISO 11607-1	2020	Packaging for terminally sterilized medical devices Requirements for materials, sterile barrier systems and packaging systems.
BS EN ISO 11737-1	2018/2021	Sterilization of health care products. Microbiological methods - Determination of a population of microorganisms on products
BS EN ISO 11737-2	2020	Sterilization of health care products. Microbiological methods - Tests of sterility performed in the definition, validation and maintenance of a sterilization process
BS EN ISO 13485	2016	Medical devices. Quality management systems. Requirements for regulatory purposes.
BS EN ISO 14602	2011	Non-active surgical implants. Implants for osteosynthesis
BS EN ISO 14801	2016	Dentistry. Implants. Dynamic loading test for endosseous dental implants
BS EN ISO 14971	2019	Medical devices. Application of risk management to medical devices
BS EN ISO 15223-1	2016	Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied - General requirements
BS EN ISO 20417	2021	Medical devices — Information to be supplied by the manufacturer
BS ISO 16142-1	2016	Medical devices. Recognized essential principles of safety and performance of medical devices - General essential principles and additional specific essential principles for all non-IVD medical devices and guidance on the selection of standards

ISO 5832-3	2016	Implants for surgery. Metallic materials - Wrought titanium 6-aluminium 4-vanadium alloy
PD CEN ISO-TR 24971	2020	Medical devices. Guidance on the application of ISO 14971.

9. AMENDMENTS

Issue	Date	Validation language	Summary of changes	Drafted by
Issue A	March 2022	English [This document has been submitted for approval]	Initial draft in accordance with the requirements of Article 32 of the Regulation	Regulatory affairs supervisor

APPENDIX 1 - COMPATIBILITY

1. OSTEOCARE INSTRUMENTS FOR (INDIRECT) USE WITH ALL IMPLANTS

- IN-USK-001 – Universal Surgical Kit
- IN-MSK-002 – Surgical Kit
- IN-RES-SET – Ridge Expander Set
- IN-ISF-SET – Socket Former Set
- IN-UBR-KIT-001 – Universal Bur Titanium Set
- IS-STS-KIT-001 – Universal Bur Stainless Steel Set
- IN-PBR-130L – Ultra Pilot Bur Long
- IN-PBR-130S – Ultra Pilot Bur Short
- IN-BRE-001 – Bur Extender
- IN-RAT-220 – Ratchet
- IN-RTE-001 – Ratchet Extender
- IN-CTF-001 – Centre Finder
- Titanium Guide Tubes

2. OSTEOCARE COMPONENTS/INSTRUMENTS FOR USE WITH ONE-PIECE IMPLANTS

2.1 Mini Post Implants with 2.35 and 2.8mm diameters

Direct use

Drivers

- IN-OHD-190 – Over-Hex Driver
- IN-OHDS-190 – Over-Hex Driver Short
- IN-BPO-190 – Bur Handpiece Driver Over-Hex

2.2 Midi Post Implants with 3.3mm, 3.8mm and 4.3mm

Direct use

Drivers

- IN-OHD-240 – Over-Hex Driver
- IN-OHDS-240 – Over-Hex Driver Short
- IN-BPO-240 – Bur Handpiece Driver Over-Hex

2.3 Mini/Midi Ball Implants (2.35mm, 2.8mm, 3.3mm, 3.8mm, 4.3mm diameters)

Direct use

Components

- CO-HMI-180 – O-Ring Housing (Black)
- CO-HMI-170 – O-Ring Housing (Red)

Drivers

- IN-OHD-240 – Over-Hex Driver
- IN-OHDS-240 – Over-Hex Driver Short
- IN-BPO-240 – Bur Handpiece Driver Over-Hex

2.4 Maxi Z, Maxi Z Flat End One-Piece

Direct use

Drivers

- IN-OHD-240 – Over-Hex Driver
- IN-OHDS-240 – Over-Hex Driver Short
- IN-BPO-240 – Bur Handpiece Driver Over-Hex

3. OSTEOCARE COMPONENTS/INSTRUMENTS FOR USE WITH TWO-PIECE IMPLANTS

All OsteoCare two-piece Implants have the same basic interface design of a 2.2mm (across flats) internal hex and an internal thread (M1.8 x 0.35mm pitch). All two-piece Implants are therefore used with 2.2mm hexagonal drivers during implant surgery.

Each two-piece Implant has a platform diameter for use most commonly with an abutment with corresponding platform diameter. Therefore, a 3.75mm Maxi Z Implant would normally be used with a 3.75mm platform diameter Screw-Retained Abutment in a simple platform-matched restoration. Exceptionally, 3.0mm platform diameter implants (the Classic Advanced Implant is the only one available in the 3.0mm range) are for use with 3.75mm platform diameter abutments.

Platform switching may be used with any combination of abutment and Implant, but the form of platform switching for which claims of superior clinical performance have been made (the treatment paradigm first documented by **Lazzara and Porter**[9] in 2006) employ larger platform diameter implants with smaller platform diameter restorations. The Maxi Z Plus range of Implants includes a minor modification to the outer coronal diameter which is designed to facilitate such platform switching, such that 5.5mm platform diameter Implants may be used with 4.5mm platform diameter abutments, and 4.5mm platform diameter Implants may be used with 3.75mm platform diameter abutments, according to this treatment paradigm.

3.1 Prosthetic components for use with two-piece Implants

Direct use

- IM-COV-[XXX]– Cover Screw
- CO-AFS-01L – Abutment Fastening Screw (Long)
- CO-AFS-01S – Abutment Fastening Screw (Short) – for use with large prosthetic angles (≥35 degrees).
- CO-SRA[X]-0[YY] – Screw-Retained Abutment
- CO-BA[X]OP-00S – One-Piece Ball Attachment (Short)
- CO-BA[X]OP-00L – One-Piece Ball Attachment (Long)
- CO-BA[X]O-0[Y]0 – Screw-Retained Ball Attachment
- CO-DCG-[XXX] – Direct Cast Gold Abutment
- CO-BCG-[XXX] – Bridge Cast Gold Abutment
- CO-DCA-[XXX] – Direct Cast Abutment
- CO-BCA-[XXX] – Bridge Cast Abutment
- CO-HCS-[XXX] – Healing Collar (Short)
- CO-HCL-[XXX] – Healing Collar (Long)

Indirect use

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[9] **Lazzara RJ, Porter SS.** Platform switching: a new concept in implant dentistry for controlling postrestorative crestal bone levels. *Int J Periodontics Restorative Dent.* 2006 Feb; 26(1):9-17.

- CO-HMI-180 – O-Ring Housing (Black) – *supported by One-Piece Ball Attachments or Screw-Retained Ball Attachments*
- CO-HMI-170 – O-Ring Housing (Red) – *supported by One-Piece Ball Attachments or Screw-Retained Ball Attachments*

3.2 Impression/modelling/trial components for use with two-piece Implants

Direct use

- CO-ITC-[X]L – Impression Transfer (Closed Tray)
- CO-ITO-[X]L – Impression Transfer (Open Tray)
- CO-TAP[X]-0[YY] – PEEK Temporary Abutment
- IN-TAS-SET – Trial Abutment Set

Indirect use

- CO-IRP-[XXX] – Implant Replica

3.3 Instrument for use with two-piece Implants

Direct use

- IN-LHD-220 – Long Handle Driver Hex
- IN-BPD-220 – Bur Handpiece Driver Hex
- IN-RCD-220 – Ratchet-Connected Driver Hex (Standard)
- IN-RCDS-220 – Ratchet-Connected Driver Hex (Short)
- IN-RCDL-220 – Ratchet-Connected Driver Hex (Long)

Indirect use (for use with Abutment Fastening Screws or Cover Screws, which have a 1.5mm hex)

- IN-LHD-150 - Long Handle Driver Hex (1.5mm)
- IN-RCD-150 - Ratchet-Connected Driver Hex (1.5mm)
- IN-RCBD-150 – Ratchet-Connected Ball Driver
- IN-TRC-01S – Torque Wrench Connector (Short)
- IN-TRC-01L – Torque Wrench Connector (Long)

4. THIRD PARTY COMPONENTS/INSTRUMENTS FOR USE WITH TWO-PIECE IMPLANTS

The following components/instruments have been designed by third party medical device suppliers specifically for use with the Implants.

4.1 Rhein83

Direct use

- OC130MZ – OT Equator (overdenture attachment)

Indirect use

- OC192ECE – Replacement Equator Cap Kit
- OC140CEV – Laboratory Cap Kit
- OC044CAIN – Equator Impression Transfers
- OC144AE – Laboratory Analogue
- OC774CHE – Equator Screwing Key
- OC091EC – Equator Cap Extractor

- OC0851AC – Equator Insertion Tool

4.2 Talladium España S.L. (Dynamic Abutment Solutions)

For use with digital workflows, the DAS abutments are available with platform diameters of 3.75, 4.5 and 5.5mm.

Direct use

- CO-TIBE-[XXX] – Dynamic Ti-Base® abutment (engaging)
- CO-TIBN-[XXX] – Dynamic Ti-Base® abutment (non-engaging)
- Dynamic Screw

Indirect use

- CO-DIRP-[XXX] – Digital Analogue
- CO-SBP-[XXX] – Scan Body
- Dynamic Screwdriver

APPENDIX 2 - SUMMARY OF CLINICAL DATA FROM OTHER SOURCES

Ref.	Literature reference	Implant	Date	Investigation	Number of implants	Result	Comment
1.	**Sethi A**, Sochor P. *Predicting Esthetics in Implant Dentistry Using Multiplanar Angulation: A Technical Note*, Int J Oral Maxillofac Implants **1995**; 10; 485-490.	Classic	1995	Technical note on the use of angled abutments and trial abutments to determine optimum emergence profile for prosthetic restoration.	See reference 3 (**Sethi, 2000**)	See reference 3 (**Sethi, 2000**)	The technical note is intended to be read with reference 3 (Sethi, 2000) below, since the technique set out herein is explicitly the one used for the study which is recorded in that paper.
2.	**Sethi A**, Harding S, Sochor P. *Initial results of the Osteo Ti implant system in general dental practice.* Eur J Prosthodont Restor Dent. **1996** Mar;4(1):21-8.	Classic	1996	Long-term performance of Classic Implants	370	98.6% survival rate at mean observation period of 32 months (17 to 49 months).	These were real-world *in vivo* clinical studies focused on (1) determining long term performance of the Classic Implant design; and (2) optimising the emergence profile of abutments with a trial abutment technique. A conventional two-stage surgery was employed, with a flap raised to prepare the osteotomy and insert the Implant(s), at which point the trial abutment set is used to identify the optimum angle for the final abutment (and any adjustment to the implant rotational position can be made). A cover screw is inserted into each Implant and the reflected flap sutured back into position. Following at least six months' healing, the Implants are uncovered at second-stage surgery. The loading protocol employed is not specified, although the restorative procedure is.
3.	**Sethi A**, Kaus T, Sochor P. *The use of Angulated Abutments in Implant Dentistry: Five-Year Clinical Results of an Ongoing Prospective Study.* Int J Oral Maxillofac Implants **2000**; 15:801-810	Classic	2000	The use of angulated abutments from 0 to 45 degrees with Classic Implants	2,261	98.6% survival rate at mean observation period of 29 months (0 to 96 months)	The principal focus of the study was the use of trial abutments and angulated final abutments to determine whether this could be an adequate treatment modality. This is an extension of the above study.
4.	**Mehanna MB**, El-Dibany RM. *Effect of calcitonin on the integration of endosseous implants.* Egyptian Dental Journal, 53, 2305:2316, July, **2007**.	Advanced	2007	The use of calcitonin for improving osseointegration	10 implants in 10 patients	100% survival rate at six months. MBL Group I – 0.48mm at six months	The study investigated the use of calcitonin (which has a role in inhibiting bone resorption and which is therefore used therapeutically as a treatment for osteoporosis) as a means of improving osseointegration. The study group showed improved bone density, albeit not statistically significant. The difference in marginal bone levels

						MBL Group II – 0.53mm at six months	followed a similar pattern. The authors determined that the effect of calcitonin administration was of limited benefit. A one-stage surgical protocol was adopted, with a flap reflected ahead of osteotomy preparation and Implant placement, and the flap replaced and sutured around a healing collar. The subsequent restorative and loading protocols are not described.
5.	**Zahran A**. *Clinical evaluation of the OsteoCare Mini and Midi implants for immediate loading of mandibular overdentures*. Implant Dentistry Today, 2:1; March **2007**	Mini/Midi Ball-Type	2008	Immediate loading with mandibular overdentures using flapless surgery	42 implants in 10 patients	100% survival rate at 24 months. MBL – 0.61mm at 24 months.	The patients were completely edentulous in the mandible and partially edentulous in the maxilla (with bridgework or removable partial denture). Patients were not excluded for having risk factors, so there were four diabetic patients and two smokers. Three to six Mini/Midi Ball Implants were placed in the mandibular interforaminal region. Osteotomy preparation was flapless transmucosal – ie, drilling was performed through the gum into the underlying bone. The osteotomy was undersized (1.3mm diameter), so that primary stability could be achieved. Loading was performed on the same day (ie, *immediate* loading), with preparation of the overdenture by chairside pick-up.
6.	**Zahran A**. *Clinical evaluation of OsteoCare Midi one-piece implants for immediate loading*. Implant Dentistry Today, 2:3; September **2008**	Midi Post-Type	2008	Immediate loading in fresh extraction sockets versus healed bony sites	84 implants in 48 patients	98.8% survival rate at 12 months' post-placement. MBL – 0.52mm in healed bony sites MBL – 0.67mm in extraction sockets	Midi Post Implants were placed in undersized osteotomies or immediately into fresh extraction sockets (extended by drilling beyond the root apex), followed by non-occlusal loading.
7.	**Aly TM**, Arafat SM. *Immediate loading of implants placed into fresh extraction sockets with periapical lesions without augmentation*. Smile Dental Journal 3(4), 6:22, **2008**	Advanced	2008	Immediate loading of implants placed into fresh extraction sockets with periapical lesions	20 implants in 20 patients	85% survival rate (three failures). As the implants were placed into extraction sockets, the marginal bone level changes were gains, not losses.	Advanced Implants were placed into fresh extraction sockets with periapical lesions, the patients were otherwise not contraindicated. The extraction sockets were extended 3-4mm beyond the root apex, and the implant was inserted until flush with the crest of the peri-implant bone. This was followed by immediate non-occlusal loading with a provisional crown. One implant was lost during the first week post-placement, indicating a loss of primary stability that the author posited could have been as a result of weakness in the buccal plate due to the periapical lesion. The authors state in relation to the three failures: "*[t]he failure in these cases was due to an error in the*

							preoperative evaluation and case selection not due to the technique itself (immediate implant placement and immediate non-functional loading)" and conclude "*proper patient/case selection is a very important factor to achieve success of this technique. The patient has to be in an ideal condition regarding any systemic health conditions that can affect the bone, performing good oral hygiene, has no parafunctional habits and with sufficient bone beyond the root apex of the tooth to be extracted. In addition, patient motivation and cooperation to follow instructions and the regular follow-up visits are crucial to achieve success. The patient has to be very understanding and willing to follow all instructions. Meanwhile, the patient should never undergo any restorative treatment without consulting the treating dentist, because any faulty restoration in the opposing dentition can cause excessive occlusal loads on the implant. The healing period after implant placement into fresh extraction socket is very critical. The bone should be left undisturbed to allow its normal healing. Therefore, any excessive functional or non-functional loading should be avoided*". The implication from this appears to be that at least two of the failures resulted from some problems related to patient discipline in keeping to the instructions on maintenance.
8.	**Zahran A**, Sukhtian TAF, Al-Kholy S. *Evaluation of a new generation of self-tapping one-piece implant in fresh extraction sockets versus healed bony sites.* Egyptian Dental Journal, 56, 1093:1102. July **2010**.	Maxi Z One-Piece	2010	Evaluation of Maxi Z One-Piece in fresh extraction sockets versus healed bony sites (with immediate loading)	20 implants in 20 patients	100% survival rate at one year. MBL – 0.69mm at six months for both healed bony sites and fresh extraction sockets.	Maxi Z One-Piece Implants were placed in undersized osteotomies (1.3mm diameter) or immediately into fresh extraction sockets (extended by drilling 2-5mm beyond the root apex), followed by non-occlusal loading. Following preparation of the abutment portion of the Implant, a provisional crown was immediately placed out of functional occlusion. The final restoration was placed and loaded after three to four months.
9.	**Fouda MA-H**, Zahran A, Moustafa MH, Alaishery SGA. *Evaluation of periimplant tissue changes following immediate implant placement.* Egyptian Dental Journal,	Maxi Z	2010	Peri-implant tissue changes for implants placed in fresh extraction sockets	21 implants in 20 patients	100% survival rate at four months. The horizontal mesial marginal gap was 0.52mm immediately post-surgery, and	Maxi Z Implants were placed in fresh extraction sockets around which a flap had been raised to visualise the crestal bone. A cover screw was inserted into the Implant and the flap was replaced into its original position and sutured. No description is provided of the restoration or loading protocols subsequently adopted.

	56, 1507:1514. July **2010**.					0.05mm at four months (ie, a decrease of marginal gap of 0.47mm); and the horizontal palatal marginal gap was 1.38mm at baseline, and 0.02mm at four months (a decrease of 1.36mm). The vertical mesial gap was 2.05mm at baseline, and 1.02mm after four months; and was 6.52mm at baseline, and 2.05mm at four months.	
10.	**Zahran A**, El-Refai M, Amir T, Fouda M. *Clinical evaluation of flapless free-hand immediate implant placement in fresh extraction sockets*. The Journal of Implant and Advanced Clinical Dentistry, vol. 2(8), October **2010**.	Maxi Z One-Piece	2010	Flapless freehand surgery for immediate placement in fresh extraction sockets and immediate loading	62 implants in 62 patients	100% survival rate. MBL – 0.70mm at one year.	Maxi Z One-Piece Implants were placed in fresh extraction sockets (no flap raised, as part of a "flapless, freehand technique") extended 3-5mm beyond the apex of the socket with a 1.3mm diameter drill. Sequential drills (2.2 and 2.75mm) were used in cases of hard bone in the socket. Following preparation of the abutment portion of the Implant, a provisional crown was immediately placed out of functional occlusion. The final restoration was placed and loaded after six months.
11.	**Zahran A**, Samy H, Mostafa B, Rafik R. *Evaluation of two different implant designs for immediate placement and loading in fresh extraction sockets.* Journal of American Science, **2010**:6(12); 1192-1199.	Midi Post-Type and Maxi Z One-Piece	2010	Two different implant designs for immediate placement and loading in fresh extraction sockets	20 implants in 10 patients (split-mouth)	100% survival rate. MBL – 0.67mm at six months for both implant designs.	Maxi Z Implants and Midi Implants were placed in fresh extraction sockets in the maxilla, with the Maxi Z selected for larger sockets and Midi for smaller. The socket was extended using a 1.3mm diameter drill 3-5mm beyond the apex of the socket. Following preparation of the abutment portion of the Implant, a provisional crown was immediately placed out of functional occlusion. The final restoration was placed and loaded after six months.
12.	**Zahran A**, Darhous M,	Midi Ball-Type	2010	One-piece implants	75 implants in 14	97.3% survival rate.	Four to six Midi Ball Implants were placed into osteotomies

	Sherien M, El-Nimr T, Mostafa B, Amir T. *Evaluation of conical self-tapping one-piece implants for immediate loading of maxillary overdentures*. Journal of American Science, **2010**:6(12); 1774-1781.			immediately loaded for maxillary overdentures	patients	MBL – 0.72mm at 12 months, 0.88mm at 18 months.	prepared with a flapless transmucosal technique. The Implants were immediately loaded.
13.	**Al-Noumas NRI**, Zahran A, Rahman RA. *Evaluation of narrow diameter implants in compromised sites.* Egyptian Dental Journal, 56, 1183:1191. July **2010**.	Mini/Midi Post	2010	Clinical success of narrow-diameter implants in horizontal atrophic ridges using freehand transmucosal flapless technique; and under-preparation of the osteotomy site.	20 implants in 9 patients	95% survival rate. MBL – 0.87mm at six months	Mini/Midi Post Implants were placed into osteotomies prepared with a flapless transmucosal technique (1.3mm diameter drill). Following preparation of the abutment portion of the Implant, a provisional crown was immediately placed out of functional occlusion. After 3-4 months, the final restoration replaced the provisional crown. The authors do not speculate on the causes of the single failure.
14.	**Reda A**, El-Refaie M, Zahran A. *Evaluation of osteotome-mediated sinus floor lifting with and without bone augmentation material with simultaneous implant placement.* Egyptian Dental Journal, 57, 1:6. July **2010**	Maxi Z Flat-End	2011	Sinus lifting with simultaneous implant placement, with or without bone augmentation	20 implants in 20 patients	95% survival rate at 12 months. MBL was not reported.	Maxi Z Flat-End Implants were placed in the posterior maxilla with 6-10mm residual bone height. The osteotomy site was uncovered with a tissue punch, and drilled to 1mm below the sinus floor. The sinus floor was infractured directly or by compression of the augmentation material, depending upon whether augmentation was performed or not. The implant was then placed. The authors do not speculate on the causes of the single failure.
15.	**Zahran A**, Mostafa B, Elfirt E, Reda A, Sukhtian T. *Evaluation of flapless osteotome-mediated sinus floor elevation with simultaneous implant placement.* Clinical and Practical Oral Implantology, vol 2(4), **2011**.	Maxi Z Flat-End	2011	Sinus lifting with simultaneous implant placement (no bone augmentation)	108 implants in 64 patients	97.2% survival and success rate (three implants in D4 bone failed to achieve primary stability and therefore did not osseointegrate). MBL – 1.02mm at one year.	Maxi Z Flat-End Implants were placed in the posterior maxilla with at least 5mm residual bone height. The osteotomy site was uncovered with a tissue punch, and drilled with sequential drilling to 1mm below the sinus floor. The sinus floor was infractured directly, and the Implant was then placed and cover screw inserted. The Implant was allowed to heal for six months before the cover screw was removed and replaced with a healing collar and allowed to heal for three to five days and definitively restored. The three implants that failed to osseointegrate had been placed in poor quality (D4) bone.

	El-Marssafy L, Ul-Dahab OA, Zahran A, Shoeib M. *Evaluation of immediately-loaded dental implants placed in healed bony sites with or without addition of autologous platelet-rich plasma*. Journal of American Science, **2011**:7(3); 633-643.	Maxi Z One-Piece	2011	Immediately-loaded implants in healed bony sites treated with or without PRF	24 implants in 12 patients (split-mouth)	100% success rate. MBL – 0.71mm (with or without PRF – there was no statistically significant difference)	Osteotomies were prepared in the posterior maxilla using a flapless transmucosal technique with sequential drilling. Platelet-rich fibrin (PRF) was injected into the test osteotomies immediately prior to Implant placement. Following preparation of the abutment portion of the Implant, a provisional crown was immediately placed out of functional occlusion. After six months, the final restoration replaced the provisional crown.
17.	**El-Wahab KAA**, Aziz EA, Nada MAE-M. *Effect of two loading protocols on the supporting structures of mini implants supporting mandibular overdentures*. Clinical and Practical Oral Implantology, vol 3(3), **2012**.	Mini Ball-Type	2012	Loading protocols for mini implants supporting mandibular overdentures	41 implants in 10 patients	97.6% survival rate (40 implants were initially placed of which one failed after one week and was replaced). MBL – was expressed as a percentage (7.0%) and was the same for the immediate and delayed loading protocols.	Mini Ball Implants were placed into osteotomies prepared in the mandible using a 1.3mm diameter drill and surgical template to guide positioning. The Implants were immediately loaded with a mandibular overdenture. There was a single failure after one week. The authors speculate that this occurred as a result of an error during the pick-up procedure which is used to position the matrix (ie, the O-ring Housing) in the overdenture, resulting in the O-ring Housing being out of position and placing too-high a stress on the Implant.
18.	**Zahran A**, Zaki BM, Medhat A. *Immediate replacement of agenic lateral incisors using one-piece Mini and Midi dental implants*. Journal of Applied Sciences Research, 9(1): 184-196, **2013**.	Mini/Midi Post-Type	2013	One-piece implants for immediate loading to replace agenic maxillary lateral incisors	14 implants in 9 patients	100% survival rate. MBL – 0.77mm at six months	A tissue punch was used to expose the underlying bone in the maxillary lateral incisor position, and drilling with a 1.3mm diameter to create the osteotomy. The Mini/Midi Post Implant was placed and prepared *in situ*, and a provisional restoration applied out of occlusal loading. After six months, the final restoration replaced the provisional crown.
19.	**Zahran A**, Abdulmaguid R, Rabie Z, Mostafa B. *Long-term retrospective clinical and radiographic follow-up evaluation of 108*	Mini/Midi Ball-Type	2016	Long-term follow-up	108 implants in 31 patients	100% survival rate (average follow-up period of 5.4 years, ranging from 5 to 11 years)	The patients were completely edentulous in the mandible and some suffered contraindications such as aggressive periodontitis, lung cancer requiring chemotherapy, and bone metabolism conditions requiring bisphosphonate therapy. 11 patients were smokers.

	OsteoCare Mini and Midi Ball-Type implants subjected to immediate loading of mandibular overdentures. Journal of Implant and Advanced Clinical Dentistry, vol 8(4) 18-29, July/August **2016**					MBL - 0.42mm	Two to five Mini/Midi Ball Implants were placed in the mandibular interforaminal region. Osteotomy preparation was flapless transmucosal – ie, drilling was performed through the gum into the underlying bone. The osteotomy was undersized (1.3mm diameter), so that primary stability could be achieved. Loading was performed on the same day (ie, *immediate* loading), with preparation of the overdenture by chairside pick-up. There were some complications related to the prosthesis, including requiring replacement of 15 O-ring Housings due to damage or loss, and two instances of broken denture. Nevertheless, there were no problems with the Implants.
20.	**Zahran A**, Mostafa B, Hanafy A, Darhous M. *A modified split-crest technique using piezoelectric surgery and immediate placement in the atrophic maxilla*. Journal of Implant and Advanced Clinical Dentistry, vol 8(4) 36-44, July/August **2016**	Maxi Z Maxi Z Flat-End	2016	Split-crest technique and immediate implant placement in atrophic maxillae	56 implants in 28 patients	100% survival rate at six months. MBL was not a measured outcome.	A flap was raised to allow access to the atrophic ridge. A piezoelectric tip was used to cut into the ridge to 1mm shorter than the length of the Implant. The osteotomy was prepared with a 3.25mm Ultra Drill and the Implant was placed immediately. Cover screws were placed on the Implants and the flap was sutured back into position over them. After six months, second stage surgery was performed to uncover the Implants and a Healing Collar was placed. The final restoration was placed 10 days later.
21.	**Zahran A**, Al Tayib F, Ali A, Sheba M. *Clinical and Radiographic Evaluation of Short Dental Implants in Posterior Atrophic Ridges with a Follow-up Period of 1 Year after Loading: A Controlled Clinical Trial*. Journal of Implant and Advanced Clinical Dentistry, vol 8(4) 36-44, July/August **2016**	Maxi Z Flat-End	2017	Short implants (6.5mm)	32 implants in 30 patients	94% survival rate at one year post-loading (two implants failed in the posterior maxilla). MBL – 1.55mm in the maxilla; and 1.10mm in the mandible at one year post-loading.	A conventional two-stage surgical protocol was adopted, with the osteotomy prepared by sequential drilling. The cover screw was inserted and the flap replaced and sutured. Second stage surgery was performed after four months and a healing collar placed for seven to 10 days before the final restoration was delivered. One failure occurred during the healing phase where it appears that primary stability was not maintained; while the other implant failed after one year of loading. The authors speculated that failure was due to poor bone quality in the posterior maxilla, and noted that the results of the study were consistent with those seen in other studies where short implants were placed in the posterior maxilla, where bone quality is lower than the mandible.
22.	**Fikry A**, Zahran A, Mahmoud H. *Clinical and*	Maxi Z Maxi Z Flat-	2021	Long-term follow-up	67 implants in 36 patients	100% survival at 12 years.	This was a retrospective study. Implants were placed in all areas of the mouth, although Maxi Z

	radiographic outcomes of functioning osseointegrated implants: a retrospective study. Implant Dentistry, 15 June **2021**	End				MBL: 1.2mm anterior maxilla; 1.3mm posterior maxilla; 1.3mm anterior mandible; 1.5mm posterior mandible.	Flat-End was placed mainly in the posterior region. Flapless surgery was used where the available ridge width was >5.5mm and free of bony defects; otherwise, a full flap was raised. Osteotomy preparation was via a sequential drilling protocol. This was a real world study, with patients presenting with various contraindications including diabetes mellitus (13.9%), smoking (16.7%), and periodontal disease (37.8%).
23.	**Zahran A**, Mortada A, Bahammam M, Elamrousy W. *Peri-implant soft and hard tissues evaluation around immediately placed new implant design: randomised clinical study.* Journal of Research in Medical and Dental Science, Vol. 9 (7), July **2021**	Maxi Z and Maxi Z Plus	2021	Prospective randomised clinical study, Maxi Z Plus versus Maxi Z (platform-switched versus platform-matched control group) placed subcrestally	114 implants in 50 patients	100% survival rate at one year post-placement for both implant types. MBL – 1.22mm for the Maxi Z; and 0.38mm for the Maxi Z Plus.	A randomised controlled clinical study, in which Implants were placed into fresh extraction sockets, with the test arm receiving the new Maxi Z Plus Implant, and the control arm receiving the Maxi Z. A full flap was raised to extract the unrestorable tooth, and the extraction socket was extended with a 3.25mm diameter Ultra Drill extending 3 to 5mm beyond the root apex. The Final Abutment was prepared and attached to the Implant, and the surgical flap was replaced and sutured. The provisional restoration was placed (non-occlusal loading), and the final restoration was cemented into position after six months.
24.	**Ashour OA**, Elbarbary AM, Elkholy SH, Zahran AF. *Evaluation of bone height gain following transcrestal sinus floor elevation using piezoelectric surgery versus the conventional osteotome technique in patients with atrophic posterior maxillae: A Randomized controlled clinical trial.* Turkish Journal of Physiotherapy and Rehabilitation; 32(3): 26482-26500	Maxi Z Flat-End (4.5mm diameter, 8 or 10mm long)	2021	Using piezoelectric surgery in sinus floor elevation surgery rather than conventional osteotome in patients with an atrophic posterior maxilla.	24 implants in 24 patients	There were no reported failures (100% survival). The study was not evaluating performance of the implants, therefore it is not possible to determine any particular areas of discussion insofar as the implants are concerned.	A randomised controlled clinical study, in which sinus elevation surgery in the control group was performed conventionally using osteotomes; and using a piezoelectric tip in the test group. A flap was raised prior to the sinus elevation surgery, and the Maxi Z Flat-End Implant was inserted immediately following the sinus elevation, until the platform was flush with the crestal bone. A cover screw was inserted into the Implant and the flap repositioned over the Implant. After six months, second stage surgery was performed to uncover the Implants, and a Healing Collar was placed. A week later, the final restoration was placed.

[10] Only available as hard copy.

	Metwaly M. *Clinical and radiographic evaluation for the use of the self tapping implant system for the replacement of missing single rooted-teeth*[10]	Midi Post	2006	Evaluation of the performance of the Midi Implant for single-tooth replacement.	10 in 10 patients (three in the maxilla and seven in the mandible).	100% survival rate at nine months. MBL – 1.12mm mean at nine months	This study showed (1) the feasibility of using a flapless surgical technique for Midi Implants; and (2) that immediate loading of missing single-root teeth could preserve dental arch integrity, occlusion, and patient satisfaction.
26.	**Yousef Y**. *Clinical and radiographic evaluation of immediately loaded dental implants placed immediately post-extraction in aggressive periodontitis patients*	Maxi Z	2007	Whether or not Maxi Z could be used in patients with aggressive periodontitis using an immediate loading protocol post-extraction. **Test group** – loading after 72 hours (six patients, 10 implants). **Control group** – loading at six months (six patients, 10 implants).	20 in 12 patients	95% overall – a single implant failure occurred in the test group.	The study sought to determine whether immediate placement and loading post-extraction of Maxi Z Implants in patients with aggressive periodontitis was a potentially viable treatment. There was a single failure in the test group (ie, 90%), and there was a 100% success rate in the control group at one year post-surgery. There was a statistically insignificant difference in peri-implant bone level between the two groups at each follow-up step (three months, six months, 12 months). The single failure was an early failure (at three weeks), whereupon the implant was removed because it showed mobility. The author did not speculate on the cause of the failure. Notably, bone density in the peri-implant bone was statistically significantly higher in the control group after one year.
27.	**Hassan IM**. *Evaluation of immediately loaded implant supplemented with single natural tooth in overdenture cases.*[11]	Midi Ball (3.3mm diameter)	2007	Mandibular overdentures retained by a single one-piece implant and a remaining tooth on the opposite side of the mandible in the canine region.	Nine implants in nine patients	89% overall – a single implant failed after a day. The author did not include the failed implants in his subsequent analysis.	The combination of a single one-piece ball implant and a single canine with a bespoke stud attachment cemented into it performed well for the purposes of retaining a removable overdenture. The surgical protocol was flapless osteotomy preparation and implant insertion followed by immediate loading. No explanation was provided by the author in relation to the failed implant, but it seems that primary stability was not achieved: this was a very early failure.
28.	**Attia MM**. *Evaluation of two different occlusal concepts used in immediately-loaded mandibular implant*	Midi Ball (3.8mm diameter, 16mm long)	2008	The study evaluated different occlusal concepts for overdentures (ie, how the opposing artificial	32 implants in 16 patients (two groups split equally)	100% survival at one year post-surgery. The patient population was fully edentulous males	Maxillae were treated with conventional removable dentures. Mandibles were treated with two-implant-supported removable overdentures retained with o-rings. The patients were split into two groups (eight in each group). The surgical protocol was flapless osteotomy preparation and

[11] Only available as hard copy.
[12] Only available as hard copy.

	overdenture [sic].[12]			teeth should interact to achieve the best results)		(45 to 65) in good health and free of systemic disease. MBL – 0.6mm and 0.7mm (not statistically significant difference) for the two groups respectively after one year.	implant insertion followed by immediate loading. The two Midi Ball Implants were placed in the mandibular interforaminal region (on opposing sides of the mandible). At loading, denture occlusion was determined according to the two occlusal concepts being studied, depending upon the patient group. The two implants adequately supported the mandibular overdenture for the period of the study. Flapless surgery with immediate loading was a suitable protocol for two-implant supported mandibular overdentures.
29.	**Selim KEM**. *Assessment of the level of cathepsin K in the crevicular fluid around early loaded single-piece dental implants during the follow-up period*.	Mini/Midi Post	2009	Assessment of the levels of an enzyme involved in bone modelling and resorption (cathepsin K) in crevicular fluid, as a potential biological marker for determining peri-implant tissue health and to evaluate failure of dental implants during follow-up.	10 implants in 10 patients.	70% survival – three implants failed	The implants were placed as single-tooth replacements in healed bony sites using a flapless protocol. Non-functional loading was applied immediately post-surgery and for two to three weeks, before (unsplinted) definitive crown placement. Mobility developed around three of the implants during the third month post-surgery, at around the time that bone remodelling usually occurs as part of the osseointegration process. The author explained that in the three failed implants, bone resorption occurred due to the development of mucositis and subsequently peri-implantitis. In those three patients, cathepsin K levels were higher than in the seven successful implants, consistent with the anticipated effect of cathepsin K being expressed by osteoclasts during excessive bone resorption (ie, leading to failure). The author noted that "*[i]n spite of giving oral hygiene instructions to all patients early in their treatment and reinforced during the subsequent appointments… it was noticed that some patients were not following the instructions after three months of the implant placement*" – no statement is made as to whether the failed implants were in patients who were not following the hygiene instructions.
30.	**Borg HS**. *Comparison between one- and two-piece immediately-loaded implant-supported lower*	Midi Ball (3.8mm diameter) Maxi Z	2009	Evaluating the performance of one-piece versus two-piece implants for the	32 implants in 16 patients (two groups split equally)	100% survival at one year post-surgery. The patient population was fully	The surgical protocol was flapless osteotomy preparation and implant insertion. The implants were placed in the mandibular interforaminal region (on opposing sides of the mandible). The author did not explain which abutments were used for the

[13] Only available as hard copy.

	complete overdenture.[13]	(3.75mm diameter)		retention of mandibular overdentures		edentulous males (45 to 65) in good health and free of systemic disease. MBL – 0.8mm for both groups after one year.	Maxi Z (ie, whether OPBA or SRBA), nor whether the same loading protocol was used and whether this was immediate or delayed or non-functional. Seemingly there was no difference in the performance of the two implant types in terms of peri-implant tissues. There is nevertheless a lack of information as to whether prosthetic complications were higher for the two-piece implants, which might be possible for example if the AFS loosens. This seems unusual given that the author refers to the ease of use of one-piece implants in his/her review of the literature thus: "…*the need to retighten the abutments seems to be eliminated with the one piece design and the one piece design might be one way of preventing bacterial leakage*", but makes no reference to having had to retighten abutments on the Maxi Z.
31.	**Murad YW**. *Clinical evaluation of transmucosal flapless implant placement using osteotomes.*[14]	Maxi Z One-Piece	2010	Evaluating the performance of unconventional osteotomy preparation using osteotomes, against conventional drilling technique, for placement of one-piece implants.	20 implants in 9 patients (split-mouth). One patient had four implants, each of the others had two. All implants were placed in the maxilla.	100% survival at six months. MBL – 0.78mm at six months. The difference between the two groups	The osteotomies were prepared deliberately undersized, principally to promote primary stability by compression of peri-implant bone as the implants were screwed into position. Provisional restorations were placed up to 48 hours after surgery to provide non-occlusal loading (in the centric and eccentric positions). After six months, the final restorations were placed. There were no statistically significant differences between the two groups in terms of the different measures used (bone density, gingival margin, plaque index, MBL), suggesting that the experimental protocol using osteotomes would have a similar rate of survival as the conventional drilling technique where undersized osteotomies were prepared. The follow-up period was short enough that longer-term conclusions cannot be drawn, particularly as the use of undersized osteotomies has been suggested in the literature as a cause of bone resorption due to micro-cracking of cortical bone and subsequent necrosis (see paragraph 6.42 of the main body of this Review, and paragraphs 81 and 82 of Appendix B).
32.	**Shaarawi AM**. *Evaluation of bone changes in extraction sockets following immediate*	Maxi Z	March 2021 (study completion	Bone grafting extraction sockets (1) for immediate or delayed implant placement	32 implants in 32 patients	100% success rate at one year post-surgery.	The purpose of the study is to assess volumetric bone changes and whether these are dependent upon the approach taken to the application of the bone graft (in the form of a xenograft).

[14] Only available as hard copy.

	implant placement or socket preservation with or without surgical flap in the aesthetic zone (Randomized clinical trial) ClinicalTrials.gov identifier: NCT3690973		)	(socket preservation); and (2) flapless or with a flap raised.			Least bone loss was observed in the preserved socket groups (ie, socket preservation with delayed implantation), with the flap reflection protocol having slightly better results than the flapless group. The implants were not the focus of the study, but none failed, and all were successful according to the criteria of the study. Randomised trial, but no blinding.