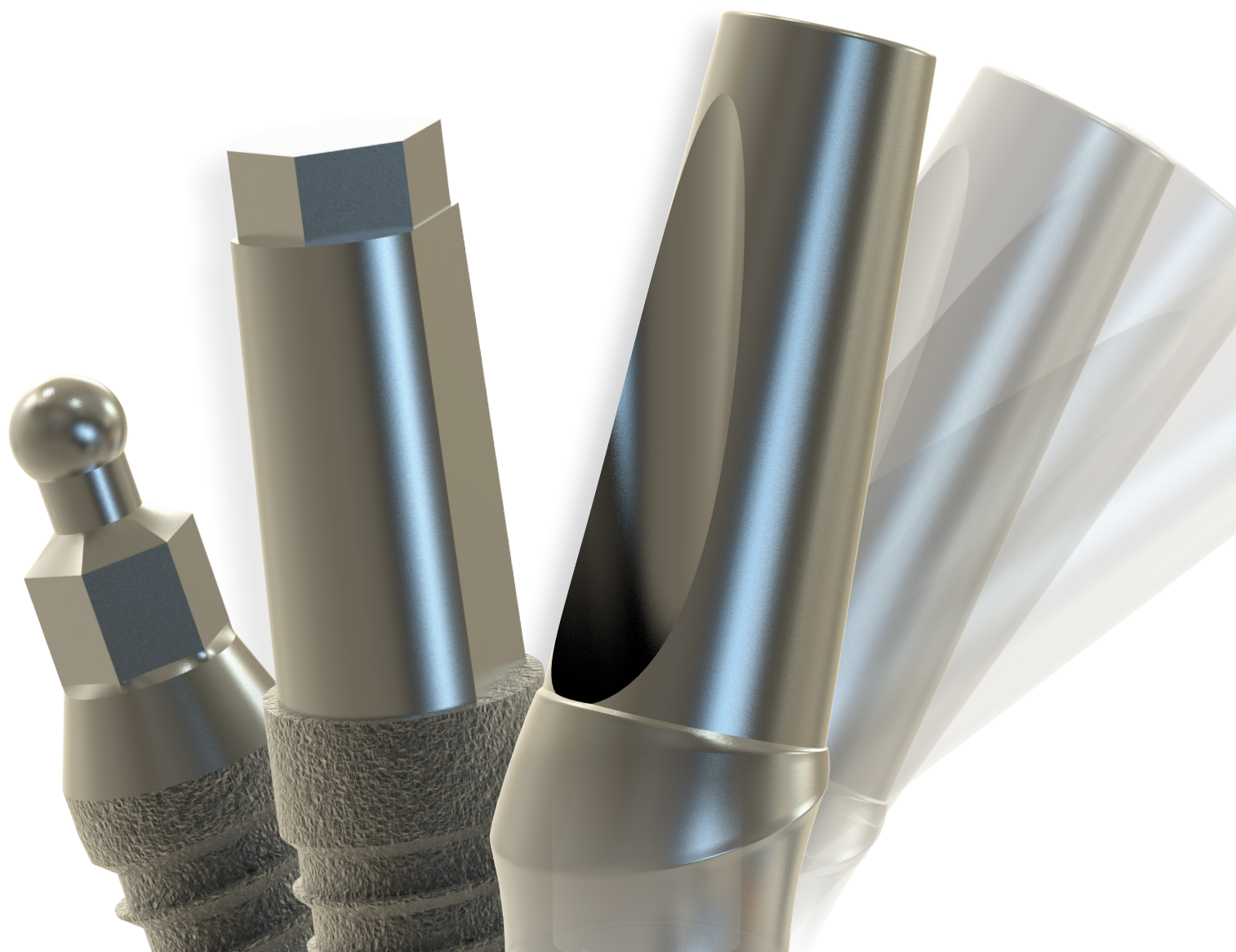


OsteoCare

Dental Implant Solutions



Growing Our Community in The Pursuit of Excellence



Clinical Manual

www.osteocare.uk.com



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Important Notice:

In order to comply with GDC guidelines, completion of an appropriate training course prior to placing OsteoCare implants is strongly advised.

Introduction

Description

OsteoCare Implant System Ltd (“OsteoCare”) manufactures dental implants, prosthetic components and surgical instruments (together, the “System”) for use by qualified, licensed clinicians and laboratory technicians fully trained in the relevant surgical and restorative techniques.

Indications

Dental implants

Dental implants from OsteoCare are used as the means of anchoring prostheses such as crowns, bridges or dentures to the bone in the upper or lower jaws.

In appropriate circumstances, where there is sufficient bone stability and appropriate occlusal loading, OsteoCare implants are intended for immediate placement and function on single tooth and/or multiple tooth restorations, including to restore chewing function. OsteoCare implants are also suitable for conventional loading scenarios.

OsteoCare implants are compatible with prosthetic components and surgical instrumentation of the System. All OsteoCare implants are manufactured from medical grade titanium alloy (6Al4V). Further details on the different available implant types and sizes, as well as guideline procedures for placement using OsteoCare surgical instruments, are set out in this Clinical Manual.

Prosthetic components

OsteoCare prosthetic components include abutments, screws, implant replicas, impression transfers, healing collars and other restorative accessories. They are manufactured from titanium alloy, gold alloy, stainless steel or polymers, all to an appropriate medical grade. OsteoCare prosthetic components are shipped non-sterile. Further details on the different available types of prosthetic components, and guideline procedures for their placement are set out in this Clinical Manual.

Please refer to the relevant instructions for use for specific requirements on sterilisation procedures of prosthetic components.

Surgical instruments

OsteoCare surgical instruments are made from stainless steel or titanium alloy and are designed specifically for use with implants and prosthetic components of the System. OsteoCare surgical instruments are shipped non-sterile. Please refer to the relevant instructions for use for specific requirements on sterilisation procedures of surgical instruments, including in particular OsteoCare burs.

System Overview

Implant Carrier System

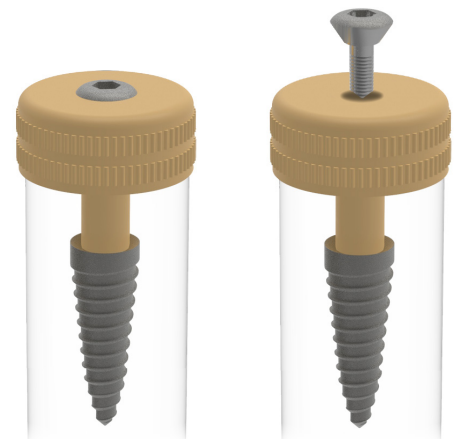
OsteoCare implants are supplied sterile. The OsteoCare carrier system enables storage without contact between the implant and the vial, allowing transport of the implant to the osteotomy whilst avoiding contact with possible contaminants which would compromise sterility. The clinician can then use the vial cap to position and drive the implant into the osteotomy until the implant driver is required. This is known as the “No Touch” technique. The carrier is designed to have a minimum number of parts and is short enough to allow access to confined spaces, whilst being long enough to allow positive grip during initial loading.



Cover Screw

The Cover Screw – supplied in the vial cap of two-piece implants – is screwed into the implant after the implant has been successfully placed. Cover Screws are made from titanium alloy and are used to block the internal hex and thread of the implants during healing where the clinician employs a delayed loading protocol. This prevents soft tissue growth and bacterial ingress into the hole.

The cover screw is removed from the vial cap using the 1.50mm hex driver. It is carried to the implant, its axis aligned to the implant axis, and inserted into the implant ensuring that there is no cross-threading. It is seated with minimal pressure. The carrier assembly is then discarded.

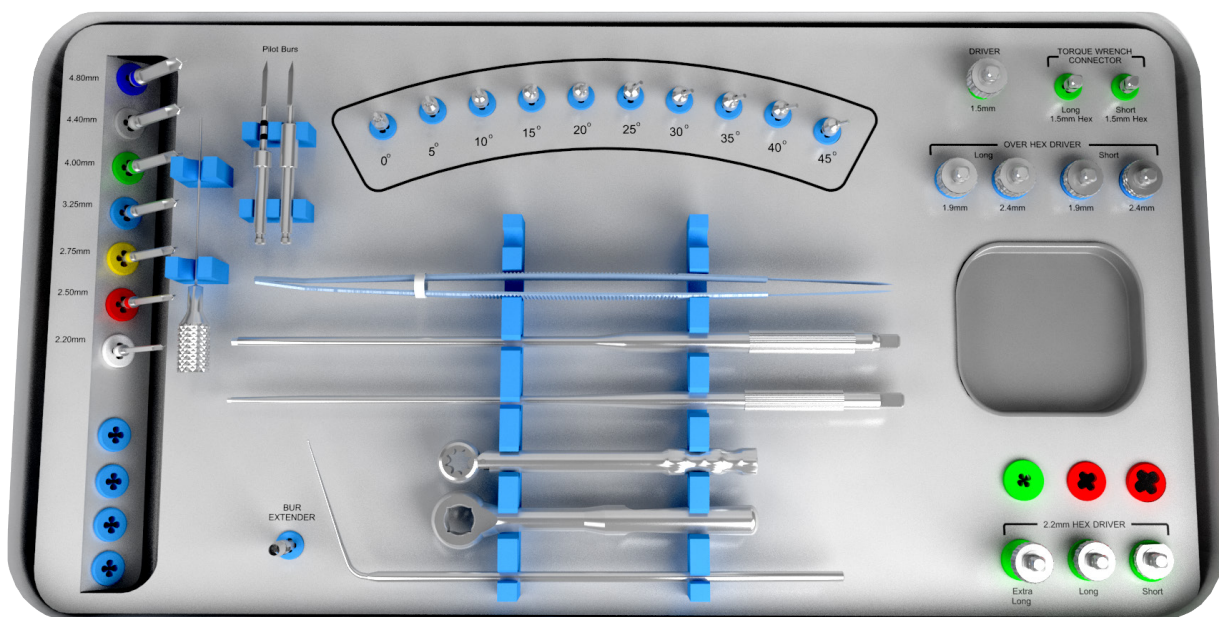


System Overview

OsteoCare surgical kits have been specifically designed to allow for ease of use, with organised layouts and clearly labelled instruments for easy return to the tray after use. All trays and contents are manufactured from materials that accept sterilisation and autoclaving.

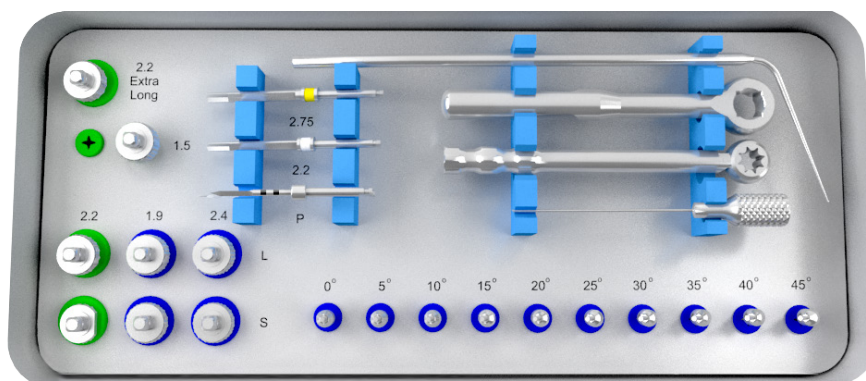
Universal Surgical Kit

The Universal Surgical Kit accommodates all instrumentation required to place Mini, Midi & Maxi Z Implants, as well as conventional Classic Advanced and Advanced Implants, providing the clinician with the facility to perform a broad range of treatment procedures.



Surgical Kit

The Surgical Kit contains all instrumentation required for the placement of Mini, Midi & Maxi Z Implants. Its simple layout benefits the clinician from an economic and organisational aspect.

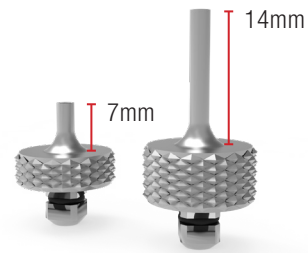


System Overview

Surgical Instruments

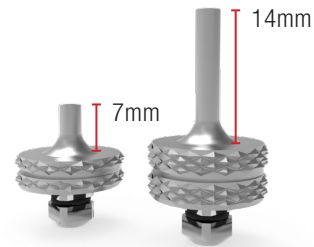
Ratchet-connected - 1.9mm Over-Hex Drivers

- For placement of Mini Implants.



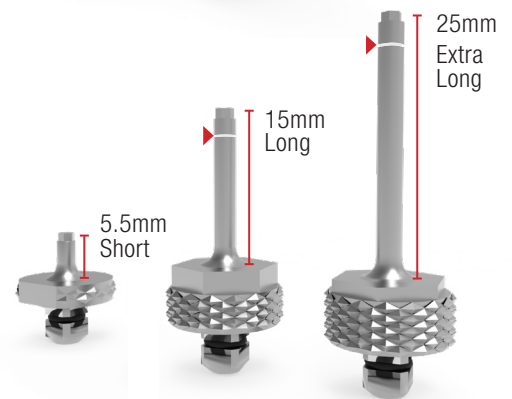
Ratchet-connected - 2.4mm Over-Hex Drivers

- For placement of Midi Implants.
- Also for placement of Maxi Z One-Piece Implants.



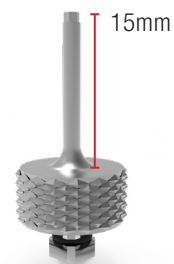
Ratchet-connected - 2.2mm Hex Drivers

- For all two-piece implants.
- Flat facets correspond with facets on the hex allowing correct orientation for abutment positioning.
- The engraved ring (marked here by the red arrow) can be used in flapless placement. In cases with 2mm gingival height, the implant is level with the crestal bone when the engraved ring is level with the soft tissue.



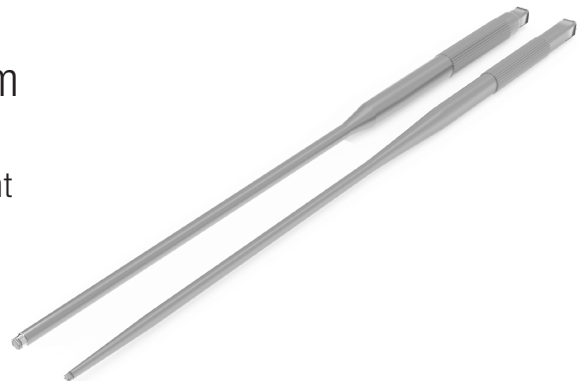
Ratchet-connected - 1.5mm Hex Driver

- For use with cover screw, abutment screw, healing collar, impression transfers.



Long-handled Hex Drivers - 2.2mm & 1.5mm

- 160mm long.
- 2.2mm driver provides enhanced control during placement in upper anterior region.
- Can be attached to the Ratchet.



System Overview

Surgical Instruments

Ratchet

- For use with the all drivers to place the full range of OsteoCare implants.

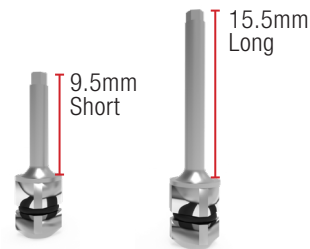


Torque Wrench 30Ncm

- To check initial stability and to place Abutment Fastening Screws to the requisite level of torque (30Ncm).

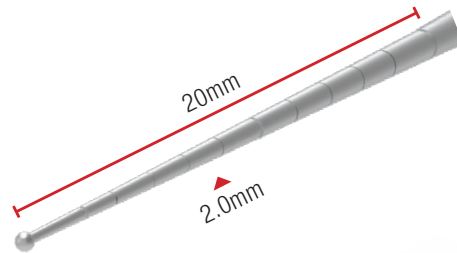
1.5mm Torque Wrench Connector

- Connects to Torque Wrench.
- Use with Torque Wrench to torque Abutment Fastening Screw to 30Ncm.



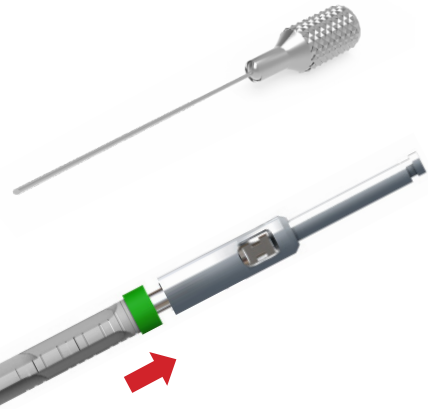
Osteotomy Probe

- 1.25mm diameter ball tip.
- 20mm long with 2.0mm graduations from tip of probe.



Bur Cleaner

- For use with internally irrigated drills.
- Used to clear the irrigation channel of any surgical debris from previous procedures prior to sterilising.



Bur Extender

- Extends working height by approx. 17mm.
- Motor hand piece attachment.
- Do not use the Bur Extender with burs of other dental implant systems, and only use OsteoCare burs.



Trial Abutments

- 0 to 45° angulation indicators in 5° increments.
- Hex fits into all two-piece implants.

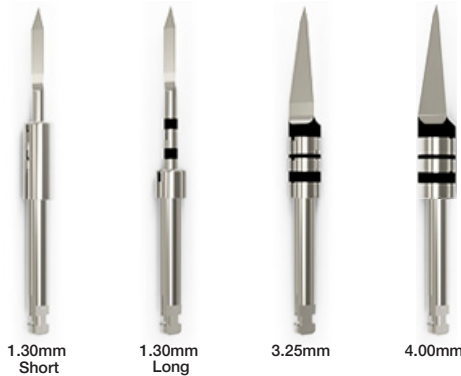
System Overview

Surgical Instruments

OsteoCare has simple yet effective burs (drills) to accommodate both tapered and parallel-profile implants.

Ultra Drills

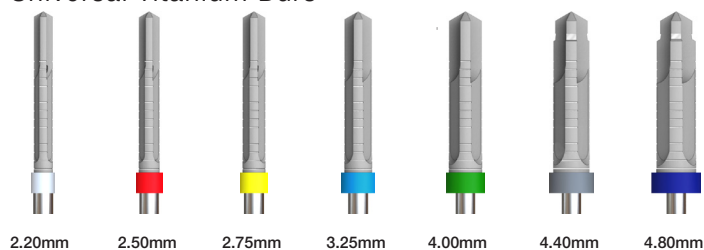
Ultra Drills provide superior accuracy for position, angle and depth with high drilling efficiency for D2-D4 bone and are triple-fluted for greater stability. The “root form” profile of the Ultra Drill is ideal for tapered implants and has proven to be successful in a one-stage drilling process.



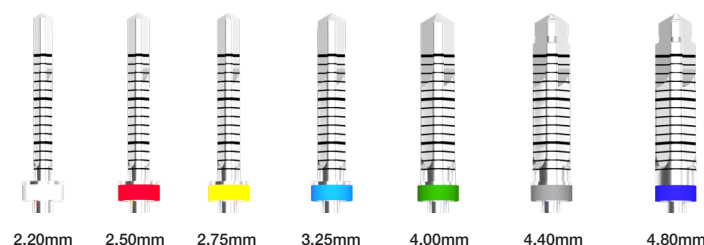
Universal Burs

OsteoCare has produced a system of sequential osteotomy universal burs with high cutting efficiency. Universal Burs are available in stainless steel with external irrigation, or internally irrigated made from titanium alloy. Both types of universal bur allow smooth, precise bone drilling at the implant site with high cutting efficiency and without excessive increase in bone temperature.

Universal Titanium Burs



Universal Stainless Steel Burs



All Burs – whether Ultra Drills or Universal Burs, should be replaced after 30 uses, or earlier if a Bur shows signs of excessive wear or where drilling efficacy is reduced. Burs must be cleaned, sterilised, and inspected before each use.

Use of a Bur beyond 30 uses, or which is worn or blunt, can lead to overheating of the peri-implant bone and consequent bone necrosis and implant failure.

Continuous, copious irrigation (both external and internal for Universal Burs, where possible) with cooled physiological saline should always be used.

OsteoCare burs shall only be used with a Type 1 dental handpiece (right angled, contra-angled, with groove and flat area and for use with a 2.35mm shank) according to ISO 1797 (Dentistry – Shanks for rotary and oscillating instruments).

System Overview

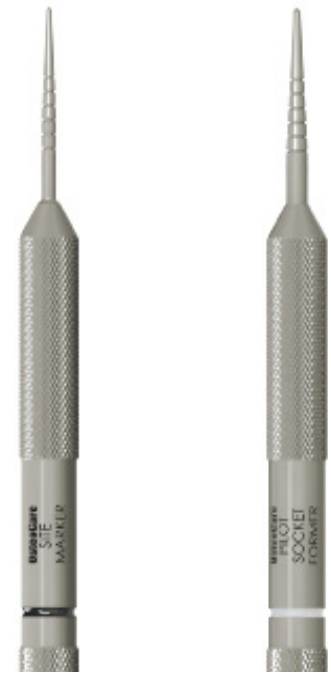
Socket Formers

OsteoCare Socket Formers are indicated for:

- osteotomy preparation;
- expansion of atrophic ridges;
- use as condensers to increase quality of soft bone;
- internal sinus floor augmentation (internal sinus lifting).

Socket Formers Pointed

For use in the preparation of an osteotomy in low density bone, the clinician first uses the Site Marker to mark the entry point. The clinician then initiates the osteotomy with the Pilot Socket Former, and then uses increasing diameter Socket Formers sequentially up to the desired size for the implant to be placed. Socket Formers may also be used as condensers in low density bone and where expansion of a narrow alveolar ridge is required.



Socket Former Set (Flat-End)

Flat-End Socket Formers are used for internal sinus lifting (osteotome-mediated sinus floor augmentation) and to place Maxi Z & Maxi Z Plus Flat-End Implants. The flat-end design of both the Socket Former and implant allows the procedure of sinus lifting to be performed reducing the possibility of perforating the Schneiderian membrane that lines the maxillary sinus.

After osteotomy preparation using sequential drilling, the socket formers are introduced by malleting to infracture the floor of the maxillary sinus. Choice of socket former diameter depends on the diameter of the implant as well as bone quality.



Flat-end

Pointed

Ridge Expanders

Ridge Expanders may be used in conjunction with socket formers and osteotomy burs if simultaneous placement of implants is undertaken. They can also be used for separation of the cortical plates for inter-positional grafting.

Intended use is for expansion of the maxillary ridge, to create adequate width for implant placement and to recontour the labial plate. The 'D' shape prevents buccal fracture by extending the expansion over a great distance and should be used with the flat side toward the palate and the convex side to the labial.

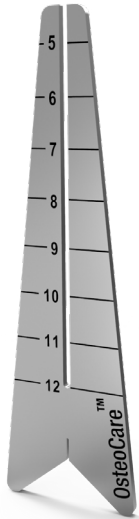


General Guidelines

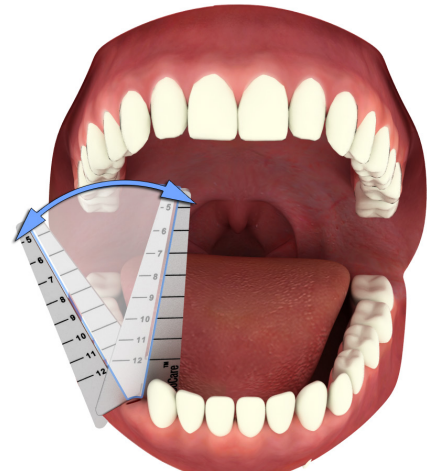
Site Marking

Centre Finder

This unique instrument is a simple tool to help find the central osteotomy preparation site in bounded areas. It also helps to measure the gap of a missing tooth to determine the correct implant diameter.



Finding central osteotomy preparation site



Finding Apical Centre

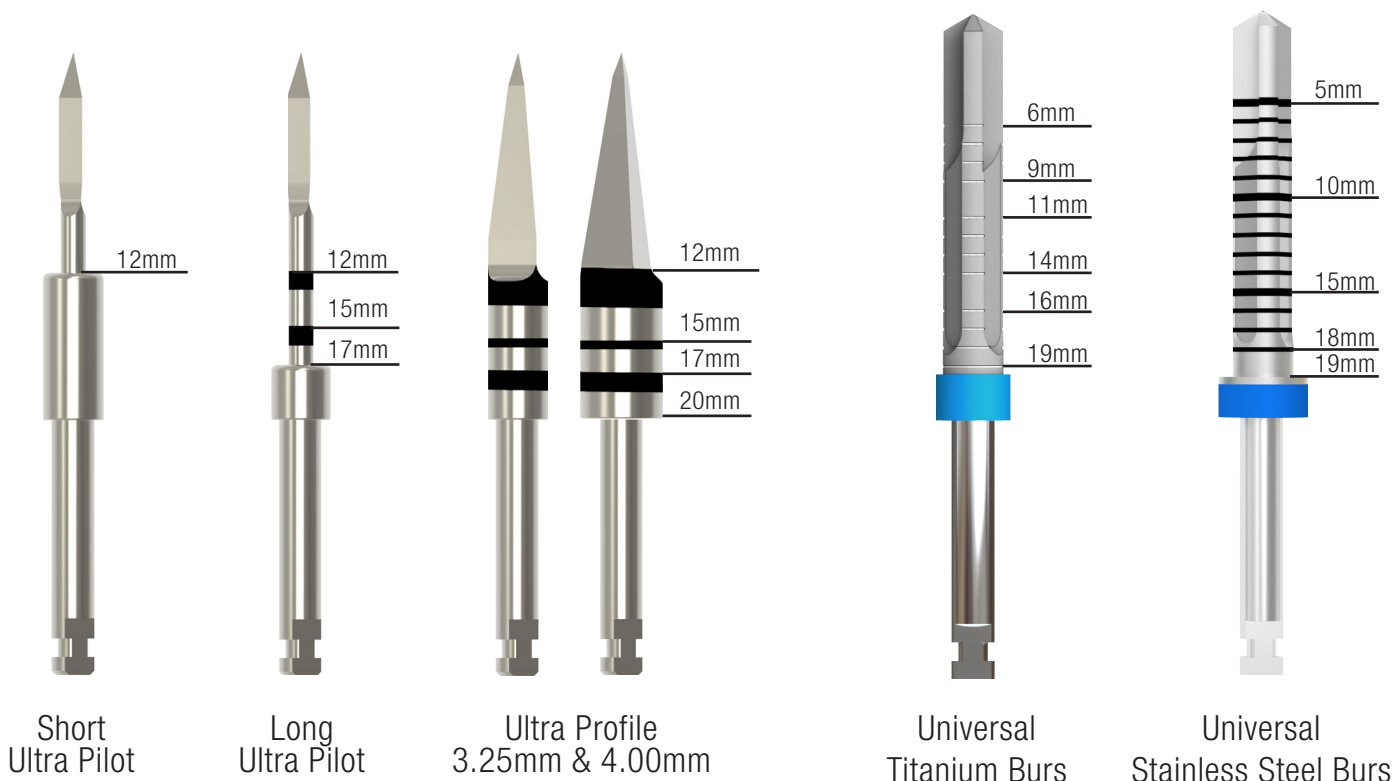
Marking the site for single implant placement

- 1- Insert the Centre Finder in the gap until it stops.
- 2- The centre of the gap is located.
- 3- Using a Tissue Marker or Scalpel mark the centre gap.
- 4- Remove the Centre Finder and proceed with operation.



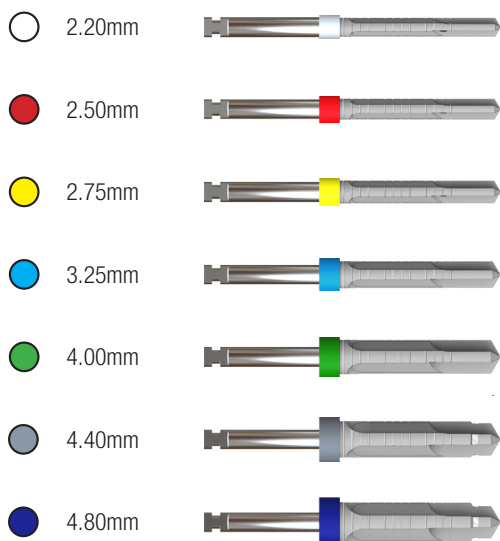
General Guidelines

Drilling depth markers



Drilling legend

Universal Titanium or Stainless Steel Burs



Ultra Drills



Drilling table sample

Bone Type	Ø 3.75mm	Ø 4.50mm
D1	Sequential options 	
D2	Sequential options 	
D3	Ultra drill size 	
D4	One drill options 	

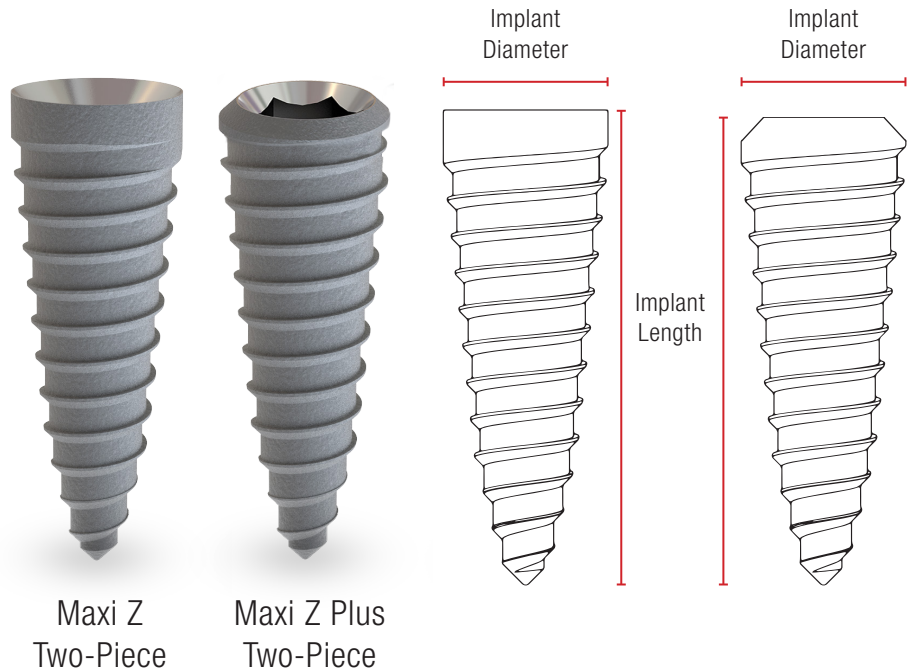


Maxi Z & Maxi Z Plus Two-Piece

OsteoCare Maxi Z & Maxi Z Plus is a tapered self-drilling, self-tapping, two-piece implant that can be used in different bone qualities. It can be placed either flaplessly or after raising a flap.

It is suitable for all the surgical approaches including placement in extraction sockets as well as healed bony sites. The prosthetic abutment designs provide excellent aesthetic solutions to restore the implant with an ideal emergence profile.

It can be used successfully in all areas of the mouth. This implant can be placed using one specially designed drill or by using conventional sequential drilling. In the lower posterior area, it is recommended to use sequential drilling as the bone is usually very dense.



Advantages:

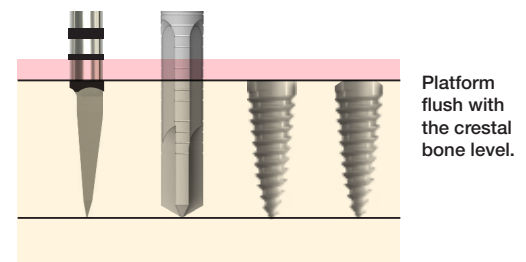
- Maxi Z & Maxi Z Plus Implants have strong self-tapping and self-drilling properties that achieve high initial stability even in low density bone;
- its platform design permits positioning of the implant according to the submerged surgical protocol;
- the platform design gives a better aesthetic emergence profile, especially in the anterior aesthetic zone and in cases with atrophic ridges;
- the two-piece restoration allows angled abutments for greater flexibility in implant positioning;
- its crestal module design results in minimal marginal bone resorption due to the protective platform that decreases the overloading of the crestal bone.

Indications:

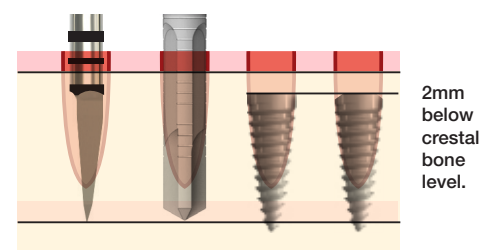
- one-stage immediate functional loading;
- one-stage delayed function;
- two-stage delayed function;
- immediate placement post-extraction and late implantation.

Notes:

- all drilling must be to the full length of the implant in healed sites;
- drill 2 to 5mm beyond the apex of the extraction socket and place the platform of the two-piece implant below the crestal bone level by 2mm; subject to bone height determined by appropriate diagnostic technique.
- Maxi Z & Maxi Z Plus Ø 5.50 Implants are intended for placement immediately post-extraction, or in a healed bony site in D2-D4 bone type.




































Healed sites














































Post-extraction

Maxi Z & Maxi Z Plus Two-Piece

Drilling guide - healed bony site

Bone type	Ø 3.75mm	Ø 4.50mm
D1	    1.30mm Ultra Pilot	     1.30mm Ultra Pilot
D2	    1.30mm Ultra Pilot  3.25mm Ultra Profile	     1.30mm Ultra Pilot  3.25mm Ultra Profile
D3	    1.30mm Ultra Pilot  3.25mm Ultra Profile	     1.30mm Ultra Pilot  3.25mm Ultra Profile
D4	 3.25mm Ultra Profile	 3.25mm Ultra Profile

Drilling guide - post-extraction

Bone type	Ø 3.75mm	Ø 4.50mm	Ø 5.50mm
D1	    1.30mm Ultra Pilot	     1.30mm Ultra Pilot	       1.30mm Ultra Pilot
D2	    1.30mm Ultra Pilot  3.25mm Ultra Profile	     1.30mm Ultra Pilot  4.00mm Ultra Profile	 4.00mm Ultra Profile
D3	    1.30mm Ultra Pilot  3.25mm Ultra Profile	     1.30mm Ultra Pilot  3.25mm Ultra Profile	 4.00mm Ultra Profile
D4	 3.25mm Ultra Profile	 3.25mm Ultra Profile	 3.25mm Ultra Profile

Maxi Z One-Piece

OsteoCare Maxi Z One-Piece Implant has a tapered self-drilling, self-tapping design. The “One-Piece” concept does away with separate prosthetic component and implant to eliminate the micro-gap found at the implant-abutment interface. This reduces any risk of bacterial ingress and abutment micro movement, each of which may affect successful osseointegration of the implant and/or successful restoration.

The Maxi Z One-Piece Implant is ideal for immediate loading post-extraction as well as placement in healed bony sites. It can also be used in different positions from the right second premolar to the left second premolar in cases with wide ridges.

One-piece implants should only be used for immediate loading, and the clinician should follow recommended guidelines for such procedures (Gapski et al., 2003).

Advantages:

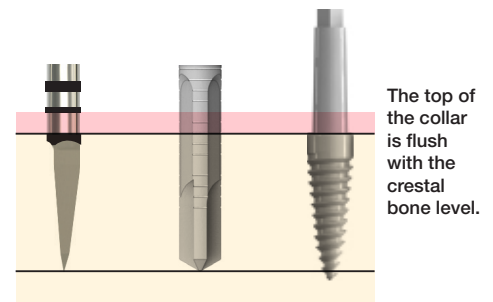
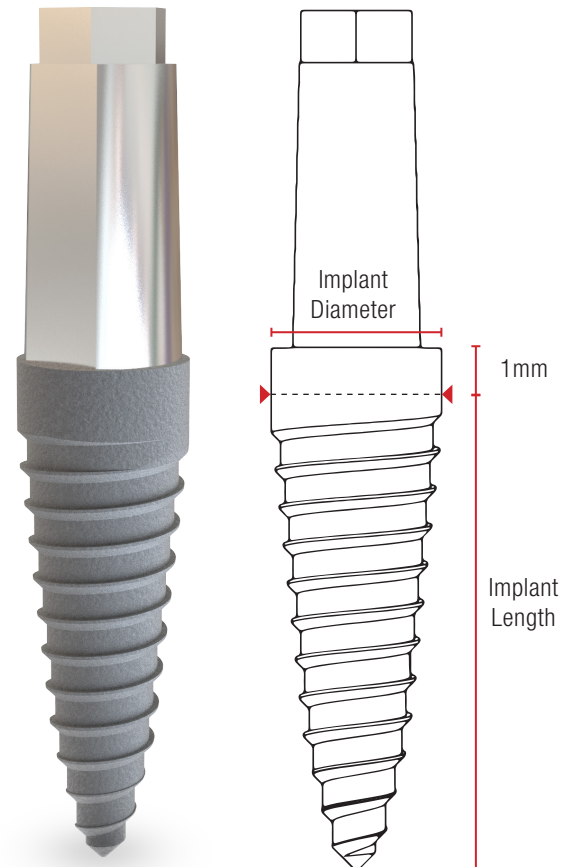
- Maxi Z One-Piece Implants have strong self-tapping and self-drilling properties that achieve high initial stability even in low density bone;
- its one-piece design eliminates the micro gap at the implant-abutment interface;
- the platform design gives a better aesthetic emergence profile, especially in the anterior aesthetic zone and in cases with atrophic ridges;
- its crestal module design results in minimal marginal bone resorption due to the protective platform that decreases overloading of the crestal bone;
- it is suitable for use in extraction sockets as well as healed bony sites.

Indications:

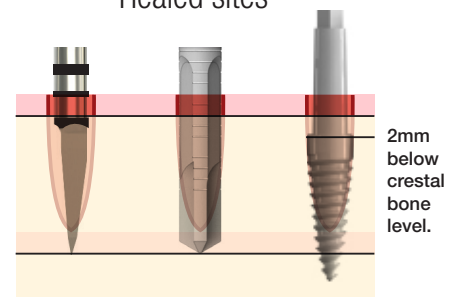
- One-stage immediate functional loading.
- Immediate post-extraction and late implantation.

Notes:

- Drill 2 to 5mm beyond the apex of the extraction socket (subject to bone height determined by appropriate diagnostic technique);
- the end of the collar should be below the crestal bone level in an extraction socket;
- the implant should be flush with the crestal bone in a healed site;
- Maxi Z One-Piece Ø 5.50 Implants are intended for use in post-extraction or healed bony site in D2-D3 bone type;
- One-piece implants are not indicated for placement post-extraction in D4 bone type;
- if placement of a one-piece implant would result in an angle which is more than 15° from the perpendicular to the occlusal plane, a two-piece implant with an angled abutment should be used instead.






































































Healed sites
















































Post-extraction

Maxi Z One-Piece

Drilling guide - healed bony site

Bone type	Ø 3.30mm	Ø 3.75mm	Ø 4.50mm	Ø 5.50mm
D1	   1.30mm Ultra Pilot	    1.30mm Ultra Pilot	     1.30mm Ultra Pilot	       1.30mm Ultra Pilot
D2	   1.30mm Ultra Pilot  3.25mm Ultra Profile	    1.30mm Ultra Pilot  3.75mm Ultra Profile	     1.30mm Ultra Pilot  4.00mm Ultra Profile	      1.30mm Ultra Pilot
D3	   1.30mm Ultra Pilot  3.25mm Ultra Profile	    1.30mm Ultra Pilot  3.25mm Ultra Profile	     1.30mm Ultra Pilot  4.00mm Ultra Profile	      1.30mm Ultra Pilot
D4				      1.30mm Ultra Pilot

Drilling guide - post-extraction

Bone type	Ø 3.30mm	Ø 3.75mm	Ø 4.50mm	Ø 5.50mm
D1	   1.30mm Ultra Pilot	    1.30mm Ultra Pilot	     1.30mm Ultra Pilot	       1.30mm Ultra Pilot
D2	   1.30mm Ultra Pilot  3.25mm Ultra Profile	    1.30mm Ultra Pilot  3.25mm Ultra Profile	 4.00mm Ultra Profile	     1.30mm Ultra Pilot
D3	   1.30mm Ultra Pilot  3.25mm Ultra Profile	    1.30mm Ultra Pilot  3.25mm Ultra Profile	 4.00mm Ultra Profile	 4.00mm Ultra Profile
D4				

Maxi Z & Maxi Z Plus Flat-End

The Maxi Z & Maxi Z Plus Flat-End Implants incorporate the design characteristics of the Maxi Z & Maxi Z Plus Implants, but with a flat end which allows placement in an atrophic maxillary ridge with lower risk of perforating the Schneiderian membrane in the maxillary sinus. It can be used in the same indicators as the Maxi Z & Maxi Z Plus Two-Piece.

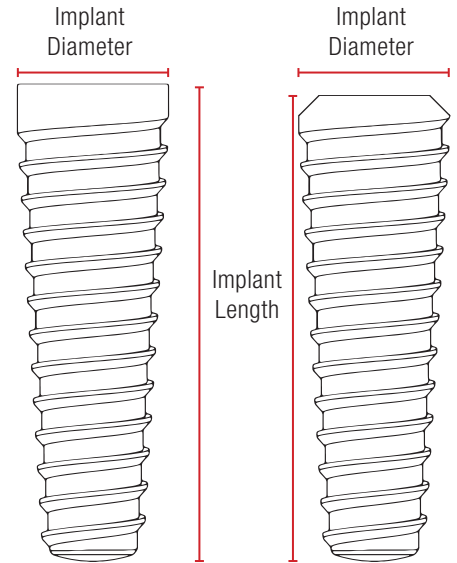
It is optionally a one or two-stage implant subject to either immediate or staged loading, where appropriate conditions prevail.



Maxi Z
Flat-End

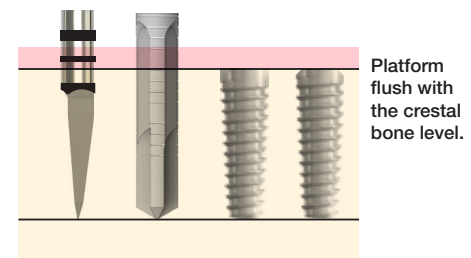


Maxi Z Plus
Flat-End

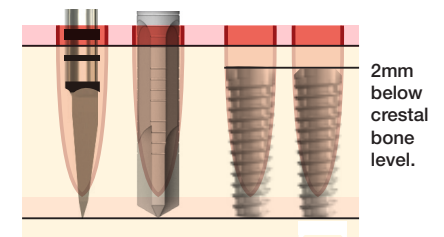


Advantages:

- flat-end and tapered design allows for sinus lifting procedure without perforating the Schneiderian membrane;
- flat-end of the implant corresponds with the existing OsteoCare flat-ended osteotomes;
- available in shorter lengths starting at 6.5mm (excluding post for one-stage implants) allowing for placement in atrophic jaws with vertical bone resorption;
- drilling protocol is similar for placement of Classic Advanced Implant. Users of the conventional system can place the Maxi Z & Maxi Z Plus Flat-End without the need for further training.



Healed sites



Post-extraction

Indications:
















- one-stage immediate functional loading;
- one-stage delayed function;
- two-stage delayed function;
- immediate placement post-extraction and late implantation.

Notes:



















- The clinician must plan adequately where there is any risk of perforating the maxillary sinus membrane;
- All drilling must be to the full length of the implant in healed sites;
- Drill 2 to 5mm beyond the apex of the extraction socket for immediate placement (subject to bone height determined by appropriate diagnostic technique);
- For sinus lifting, a bone height of more than 5mm under the sinus floor is required (determined with an OPG or CBVT);
- The osteotomy depth should be 0.5mm from the sinus floor.

Maxi Z & Maxi Z Plus Flat-End

Drilling guide - healed bony site

Bone type	Ø 3.75mm	Ø 4.50mm	Ø 5.50mm
D1	 1.30mm Ultra Pilot	 1.30mm Ultra Pilot	 1.30mm Ultra Pilot
D2	 1.30mm Ultra Pilot  3.25mm Ultra Profile	 1.30mm Ultra Pilot	 1.30mm Ultra Pilot
D3	 1.30mm Ultra Pilot  3.25mm Ultra Profile	 1.30mm Ultra Pilot	 1.30mm Ultra Pilot
D4	 1.30mm Ultra Pilot  3.25mm Ultra Profile	 1.30mm Ultra Pilot	 1.30mm Ultra Pilot

Drilling guide - post-extraction

Bone type	Ø 3.75mm	Ø 4.50mm	Ø 5.50mm
D1	 1.30mm Ultra Pilot	 1.30mm Ultra Pilot	 1.30mm Ultra Pilot
D2	 1.30mm Ultra Pilot  3.25mm Ultra Profile	 1.30mm Ultra Pilot  3.25mm Ultra Profile	 1.30mm Ultra Pilot
D3	 1.30mm Ultra Pilot  3.25mm Ultra Profile	 1.30mm Ultra Pilot  3.25mm Ultra Profile	 1.30mm Ultra Pilot
D4	 1.30mm Ultra Pilot  3.25mm Ultra Profile	 1.30mm Ultra Pilot  3.25mm Ultra Profile	 1.30mm Ultra Pilot

Mini/Midi Post-Type & Ball-Type

Mini/Midi Implants are one-piece dental implants, with unique features that set them apart from their conventional counterparts. They are ideal for immediate loading in most bone qualities and quantities including in thin atrophic ridges.

OsteoCare has produced a range of Ball and Post-Type Mini and Midi one-piece implants with a grit-blasted and acid-etched (GBA) surface treatment on the high load buttress thread. This thread form has the advantage of allowing for the compression and expansion of the site, achieving high stability even in poor quality bone.

Advantages:

- single drill technique allows for quick and simple implant placement;
- maximum primary stability in all types of bone due to the buttress thread design;
- bone expansion and compression during implant insertion, making it less traumatic for the patient.

Indications:

- one-stage immediate functional loading;
- immediate placement post-extraction and late implantation (post-type only).

Mini/Midi Post-Type Implants

These are particularly advantageous for restoring lower central or lateral teeth or upper lateral incisors. They can also be used in different positions from the right second premolar to the left second premolar especially if the bucco-lingual width of the bone is 4 to 6mm.

If the mesio-distal gap is small and cannot accommodate a Maxi Z or Maxi Z Plus Two-Piece Implant then a narrow diameter Midi Post Implant can be used, provided that the emergent post angle is not disadvantageous for restoration purposes. It is therefore very important to assess implant angle and emergence profile before placement: if an angle of 15° or more will be needed then a two-piece implant and appropriately angled Screw Retained Abutment (SRA) should be used instead.

Mini/Midi Ball-Type Implants




Mini and Midi Ball-Type Implants are particularly advantageous for mandibular overdentures and they are mainly indicated for placement in the inter-foraminal region for two-implant supported overdentures. They may also be used to support maxillary overdentures if the ridge of the upper jaw has suitable bone volume and is of sufficient quality to permit suitable placement and angulations and high primary stability for immediate loading. Again, the implant angle and emergence profile must be assessed to ensure that the axis of the implant does not exceed 15° from the vertical. If it does, then a two-piece implant and appropriately angled Screw-Retained Ball Abutment (SRBA) should be used.

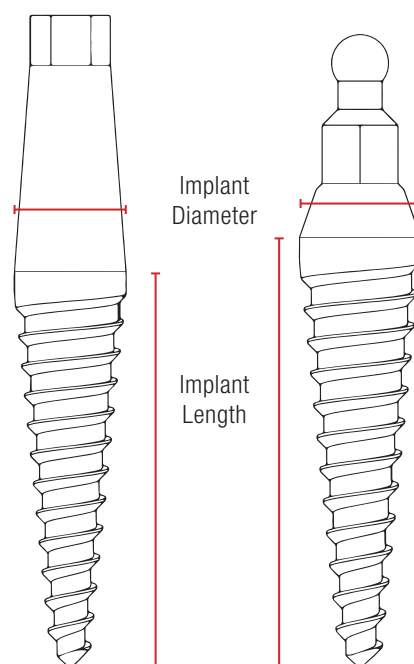
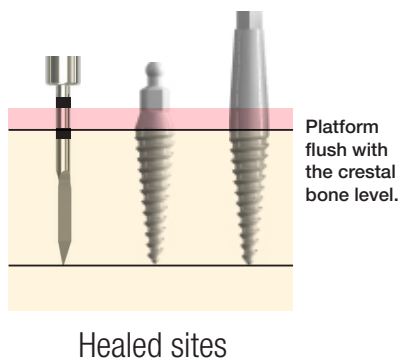
In any event, accurate analysis and planning is of particular importance for implant placement and restorations involving maxillary overdentures, including caution around the maxillary sinus, and clinicians should avail themselves of the latest literature to ensure the use of optimal techniques and the latest clinical evidence, including in relation to the number of implants required.





Mini/Midi Post-Type & Ball-Type

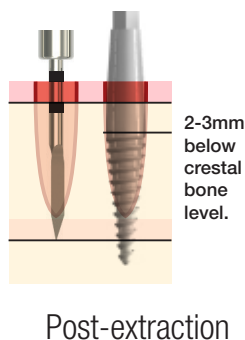
Drilling guide - healed bony site

Bone type	All diameters
D1	 1.30mm Ultra Pilot
D2	 1.30mm Ultra Pilot
D3	 1.30mm Ultra Pilot
D4	



Post-Type drilling guide - post-extraction

Bone type	All diameters
D1	
D2	 1.30mm Ultra Pilot
D3	 1.30mm Ultra Pilot
D4	



Notes:

- all drilling must be to the full length of the implant in healed sites;
- for the Mini/Midi Ball Type Implant the top of the thread should be flush with the crestal bone level in healed sites;
- drill 2 to 5mm beyond the apex of the extraction socket (subject to bone height determined by appropriate diagnostic technique);
- for the Mini/Midi Post-Type the top of the thread must be 1mm below crestal bone level in healed bony site and 2mm below crestal bone level in extraction sockets.
- One-Piece Ball-Type Implants should not be placed immediately post-extraction except by experienced clinicians.

Advanced & Classic Adv.

Advanced & Classic Advanced Implants are straight two-piece implants with an internal hex connection.

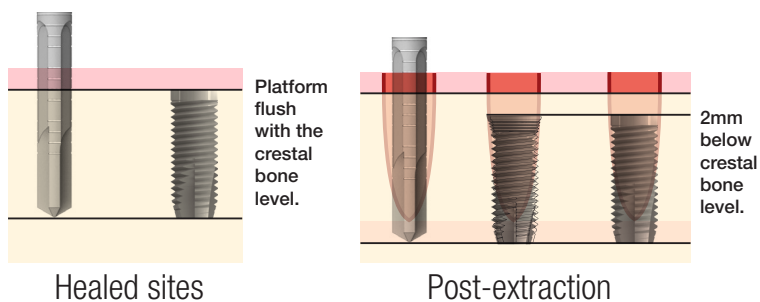
These implants incorporate a twin-start thread that provides faster implant insertion and higher initial stability. The Advanced Implant has a micro-grooved flared (tapered) head which facilitates immediate retention within the socket.

Advantages of flared head:

- increased implant-to-bone contact enhances primary stability when placed immediately post-extraction;
- reduced need for a bone graft to fill the gap between the crestal part of the extraction socket and the implant;
- enables optimal emergence profile and enhanced aesthetics;
- improves contact with cortical bone, reducing the risk of inadvertent displacement into the maxillary sinus.

Indications:

- one-stage immediate functional loading;
- one-stage delayed function;
- two-stage delayed function;
- immediate post-extraction and late implantation.



Notes:

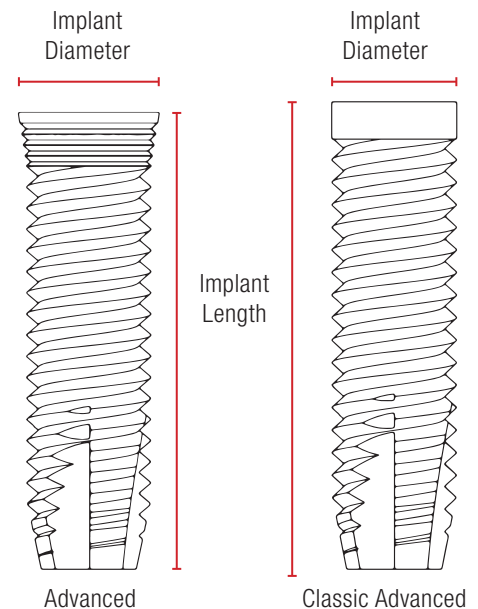
- all drilling must be to the full length of the implant in healed sites;
- Advanced Implant to be used in post-extraction sockets only.
- drill 2 to 5mm beyond the apex of the extraction socket (subject to bone height determined by appropriate diagnostic technique).



Advanced











Classic Advanced















Advanced & Classic Advanced













Advanced drilling guide - post-extraction

Bone type	Ø 3.75mm	Ø 4.50mm
D1	 1.30mm Ultra Pilot	 1.30mm Ultra Pilot
D2	 1.30mm Ultra Pilot	 1.30mm Ultra Pilot
D3	 1.30mm Ultra Pilot	 1.30mm Ultra Pilot
D4	 1.30mm Ultra Pilot	 1.30mm Ultra Pilot

Classic Advanced drilling guide - healed bony site

Bone type	Ø 3.30mm	Ø 3.75mm	Ø 4.50mm
D1	 1.30mm Ultra Pilot	 1.30mm Ultra Pilot	 1.30mm Ultra Pilot
D2	 1.30mm Ultra Pilot	 1.30mm Ultra Pilot	 1.30mm Ultra Pilot
D3	 1.30mm Ultra Pilot	 1.30mm Ultra Pilot	 1.30mm Ultra Pilot
D4	 1.30mm Ultra Pilot	 1.30mm Ultra Pilot	 1.30mm Ultra Pilot

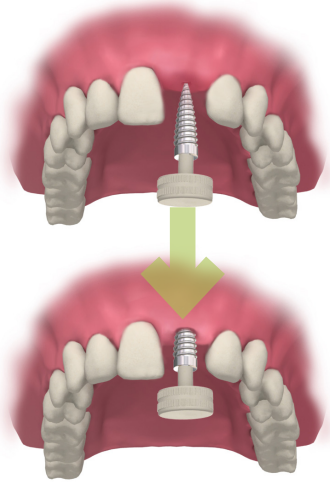
Classic Advanced drilling guide - post-extraction

Bone type	Ø 3.30mm	Ø 3.75mm	Ø 4.50mm
D1	 1.30mm Ultra Pilot	 1.30mm Ultra Pilot	 1.30mm Ultra Pilot
D2	 1.30mm Ultra Pilot	 1.30mm Ultra Pilot	 1.30mm Ultra Pilot
D3	 1.30mm Ultra Pilot	 1.30mm Ultra Pilot	 1.30mm Ultra Pilot
D4	 1.30mm Ultra Pilot	 1.30mm Ultra Pilot	 1.30mm Ultra Pilot

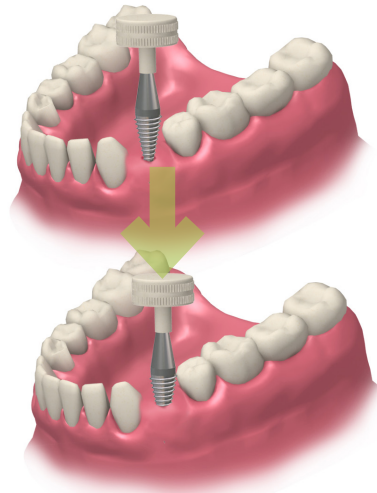
Implant Placement

PEEK Implant Carrier

Implants are supplied within sterile packaging. Peel the outer envelope of the packaging to expose the inner vial and drop this into the surgical tray. The implant is removed from the vial and offered to the prepared osteotomy via the PEEK (polyether ether ketone) carrier, taking care not to contaminate the implant surface by contact with non-sterile items. The implant is inserted into the osteotomy and rotated clockwise for several revolutions or until finger-applied torque to the plastic carrier cap can no longer easily rotate the implant.



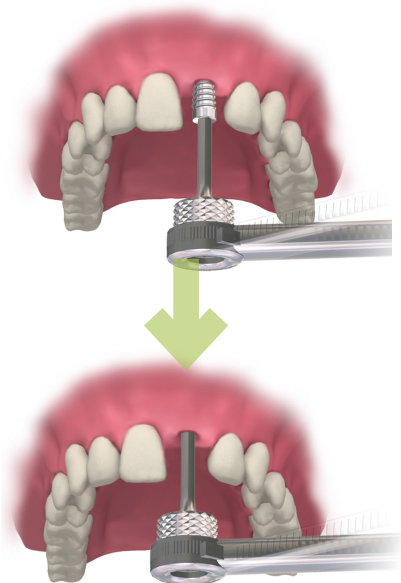
(Fig 1)



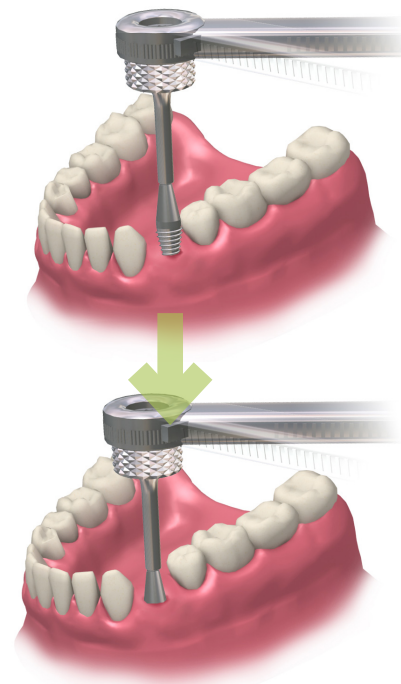
(Fig 2)

Ratchet

The PEEK carrier is removed and the appropriate drivers selected for seating the implant. One-piece implants are screwed in using the Ratchet until the top of the implant thread is flush with the crestal bone level as indicated by radiographs; while two-piece implants should be screwed in until the platform is flush with the crestal bone level. (Fig 4)



(Fig 3)

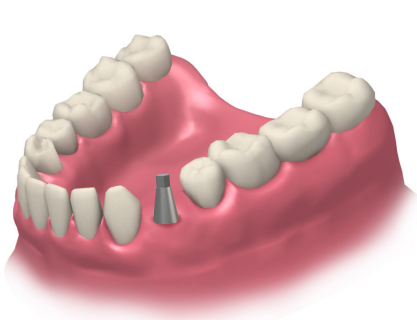


(Fig 4)

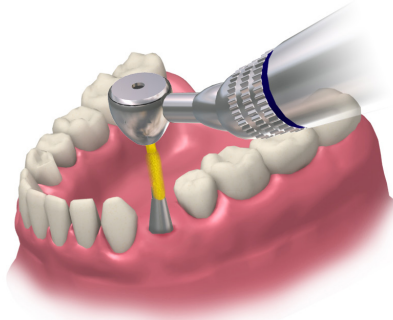
Restorative Phase

One-piece implants

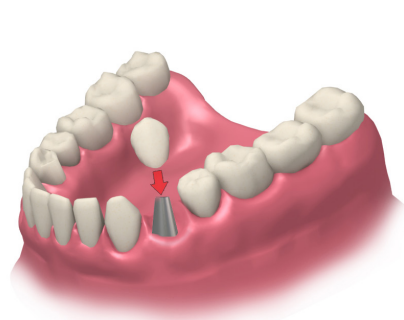
Preparation of the abutment can be performed by using a diamond or carbide high-speed bur to adjust height of the abutment section, if necessary. Abutment preparation should always be performed with copious irrigation to prevent overheating of the implant, which could otherwise damage peri-implant bone.



(Fig 5)



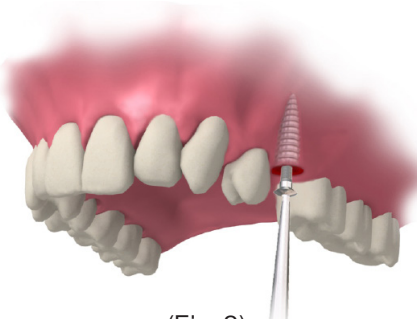
(Fig 6)



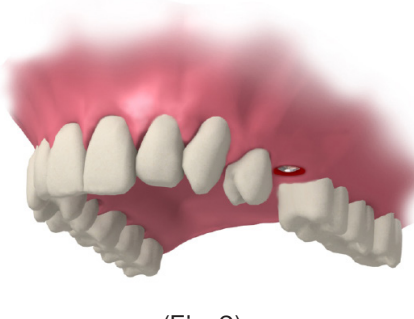
(Fig 7)

Two-piece implants

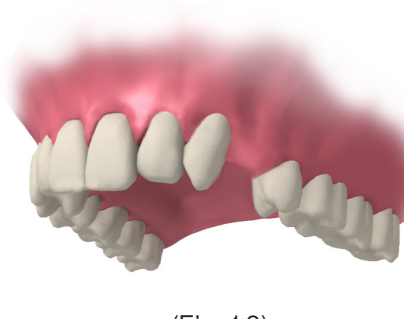
After placement, the Cover Screw is fitted to allow for undisturbed healing. This will be followed by second-stage surgery using a soft tissue punch to uncover the cover screw after a healing period of three to four months.



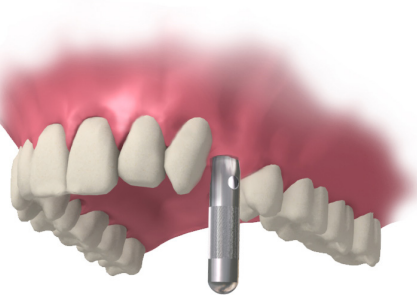
(Fig 8)



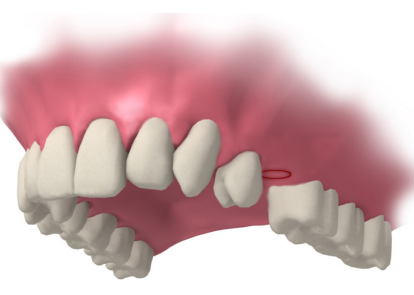
(Fig 9)



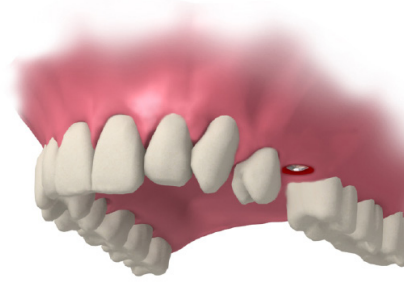
(Fig 10)



(Fig 11)



(Fig 12)



(Fig 13)

Restorative Phase

Abutments

OsteoCare produces components for temporary and permanent restorative solutions for use with our range of implants, as well as accessories for use during surgical and restorative phases.

Temporary components include Cover Screws and Healing Collars, designed for medium-term use (up to six months) to promote tissue healing in two-stage surgical procedures; as well as PEEK Transfer Abutments for short-term use (up to 30 days).

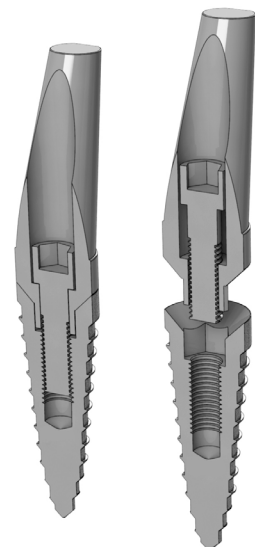
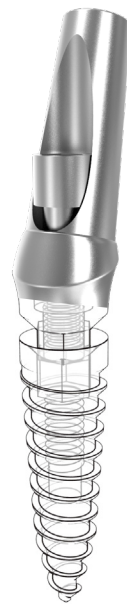
Components for permanent restorative solutions (final abutments) include those made from titanium alloy (6Al4V) such as Screw-Retained Abutments (SRAs), One-Piece Ball Abutments (OPBAs), Screw-Retained Ball Abutments (SRBAs); and a range of abutments for “cast-on” procedures such as the Direct Cast Abutments (DCAs), Direct Cast Gold Abutments (DCGAs) and Direct Cast Bridge Abutments (DCBAs) which are made from gold alloy and/or a plastic (polyoxymethylene) which is burnt away during the casting process in the laboratory.

While temporary components are designed to protect healing tissue prior to final restoration, final abutments are used to connect single or multi-unit restorations, such as fixed crowns, bridges or overdentures, to the implant, and to do so in a way that transfers occlusal and lateral forces to the implant without compromising the long-term survival of the implant.

Prior to attaching the abutment to the implant, the inner part of the implant needs to be thoroughly cleaned and rinsed. To check for the correct seating of the abutment on the implant, and of the prosthesis on the abutment, it is recommended that X-rays be taken.

Internal hex connection

The OsteoCare internal hex connection system was created by a team of top clinicians and precision engineers. The internal hex connection allows better fixation of prosthetic components and an even distribution of masticatory forces with micro-movements reduced to a minimum level. The OsteoCare internal hex distributes forces deep within the implant, shielding the retention screw from excessive loading.



Restorative Phase

Screw Retained Abutment (SRA)

SRA's come in diameters of 3.75mm, 4.50mm and 5.10mm with a 2.2mm-wide external hexagon for anti-rotational telescopic fixation to the implant internal hexagon. They are available with angles of 0 to 45 degrees (between the long axis of the implant and long axis of the restoration) at increments of 5 degrees. This provides ten different angulations for the clinician, and associated flexibility to deal with implants which are inclined with respect to the ideal, for example in order to avoid anatomical structures (eg, as an alternative to zygomatic implants in the maxilla).

The required angle of SRA is assessed by means of a Trial Abutment set, which is provided with the Universal Surgical Kit or which can be acquired separately. Trial Abutments are also made of titanium alloy (6Al4V) and are available in the same angles as SRA's, so that the clinician can assess the precise emergence angle suitable for restoration using the Trial Abutment set and then place the matching SRA. SRA's can be modified to the requisite size in the laboratory or chair side if necessary where diamond or carbide burs together with the Abutment Preparation Handle may be used.

At the stage of restoration delivery, the SRA is seated and fixed to the implant internal hexagon by an Abutment Fastening Screw (AFS). The AFS has a 1.5mm hexagon and is tightened to 30Ncm with the Ratchet and 1.5mm Torque Wrench Connector and checked by using the Torque Wrench and 1.5mm Torque Wrench Connector. The AFS should be allowed to settle for 10 minutes and then further tightened and checked- please see "AFS tightening procedure" (page 28).



SRA 0°



SRA Angled



Abutment Fastening
Screw

Restorative Phase

One-Piece Ball Abutment (OPBA) and Screw-Retained Ball Abutment (SRBA)

OPBA and SRBA are abutments comprising a 2.0mm ball at the coronal end for retention in overdentures into which have been seated an O-Ring Housing. The retention force between the rubber o-ring and the ball provides a simple and effective means of securing overdentures, particularly for completely edentulous patients, at a significantly lower cost than full restorations.

The OPBA is used to accommodate implant angulations from 0 degrees to 15 degrees; SRBAs are available at angles of 20, 30 and 40 degrees (between the long axis of the implant and long axis of the SRBA), and allow up to 5 degrees of freedom between ball and o-ring such that a 20-degree SRBA effectively covers an angular range of 15 to 25 degrees. Accordingly, OsteoCare's range of ball abutments covers all angles from 0 to 45 degrees.

The OPBA is seated and fixed to the implant directly by means of a 2.4mm Over Hex Driver and tightened to 30Ncm (checked with the Torque Wrench). The OPBA should be allowed to settle for 10 minutes and then re-tightened in the same way as in the AFS tightening procedure. The SRBA is seated and fixed to the implant internal hexagon in the same way as the SRA, namely by means of the AFS tightened in accordance with the AFS tightening procedure (page 28). OPBA/SRBA are then processed chairside or at the dental laboratory for alignment, and retention of the O-Ring Housing into the denture base is performed at the laboratory.

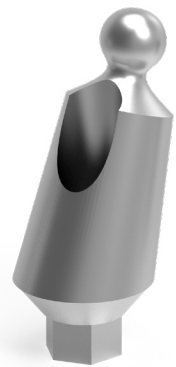
Once positioning of the O-Ring Housings into the overdenture is complete, it is important to advise patients of appropriate cleaning regimens to ensure that the fit between the overdenture and the balls is not impeded by a build up of plaque or food debris.

O-Ring Housing

O-Ring Housings are made from polycarbonate, with the o-ring retained within the housing. There are two available retentive options: the black o-ring provides a "normal" retention force for cases where four or more implants are placed; the red o-ring may be used where the overdenture is anchored to fewer than four implants or in special cases where extra retention is required.



One-Piece
Ball Abutment



Screw Retained
Ball Abutment



Polycarbonate 'O' Ring
Housing

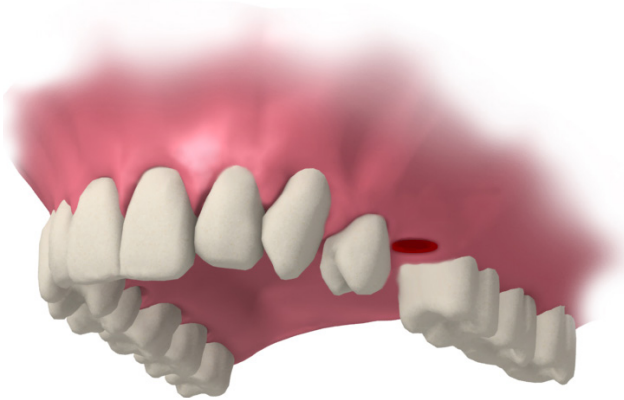
Restorative Phase

PEEK Transfer Abutment

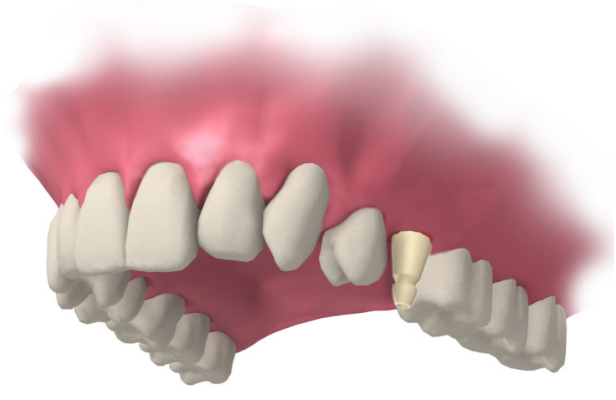
The PEEK Transfer Abutment is made from polyether ether ketone (ie, PEEK) plastic. It can be used as a provisional abutment to support a temporary (no longer than 30 days) single or multi-unit restoration. After implant placement at first stage surgery, the PEEK Transfer Abutment is secured to the implant using an AFS and the form of the surrounding mucosa is marked on the surface of the PEEK Transfer Abutment. This can then be modified according to the desired temporary restoration in the laboratory. The AFS is covered with Teflon tape and the prefabricated crown is relined to fit. Alternatively a temporary crown is made chair-side and secured with temporary cement.



PEEK Transfer Abutment



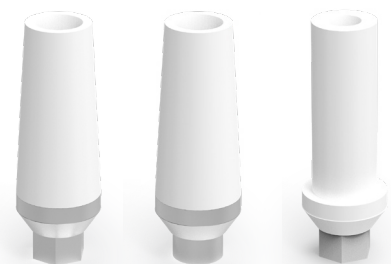
(Fig 14)



(Fig 15)

Direct Cast Abutment

The Direct Cast Abutment (DCA) is used for the fabrication of custom made abutments and screw-retained restorations, using a wax-up and cast-on technique to facilitate the fabrication of screw-retained prostheses. The DCA is also available with a gold interface (i.e. the DCGA) for a precise implant-abutment connection. The DCGA has an external hexagon which allows indexing and an anti-rotation element for single-tooth restorations; while DCBAs have the same gold interface but without the external hexagon, since the anti-rotation element is provided by the multi-unit (ie, multiple implant) restoration. The lack of external hexagon also allows slightly greater flexibility during the making of the restoration. Each of the DCA, DCGA and DCBA is attached to the relevant implant using an AFS tightened in accordance with the AFS tightening procedure (page 28).



Direct Cast Abutments

Restorative Phase

Impressions - Direct technique:

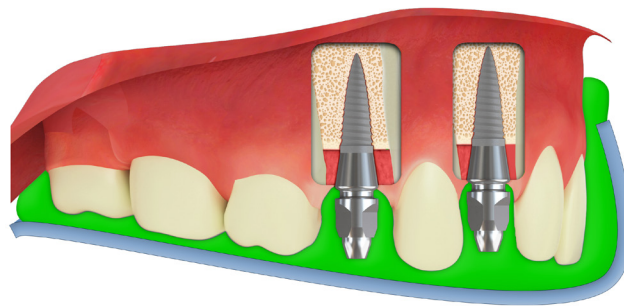
Direct impression is taken using elastomeric impression material in a sterile metal-rimmed impression tray. The impression is removed from the patient's mouth and the tray is sent to the dental laboratory. When using a Mini/Midi Post Type or Maxi Z One-Piece Implant, the prepared abutment should be treated as a normal crown and bridge case.

Impressions - Indirect technique

The Healing Collar or Cover Screw is removed. The appropriate Impression Transfer is selected then located into the internal hex and secured with the Impression Transfer Screw, which is hand-tightened using a 1.5mm driver. The hex on the head of the impression screw is blocked with red carding wax to prevent ingress of the impression material. As a general rule, the clinician should take a periapical radiograph to check the Impression Transfer is seated correctly.

Closed Tray Transfer - Closed Impression Tray

For the closed tray impression transfer technique, the dentist will use the short screw with the impression transfer and a stock tray is used for taking the impression. (See Fig 16)

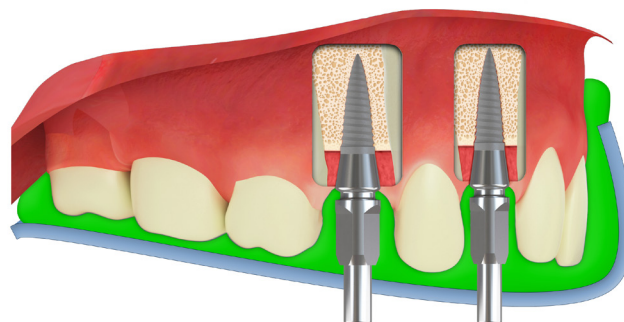


(Fig 16)

Open Tray Transfer - Open Impression Tray

For the open tray impression transfer technique, a perforated special tray is used in conjunction with impression transfer and long screw. (See Figure 17)

For both techniques, the impression is taken using a conventional addition, condensation silicone or polyether impression material. After the impression has been taken, the impression transfer is attached to the corresponding implant replica and the working model is poured at the laboratory.



(Fig 17)

Restorative Phase

O-Ring Housing pickup for implant overdentures

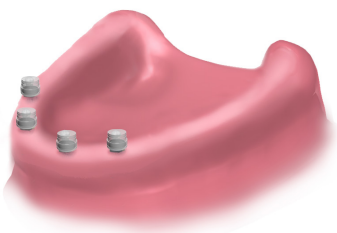
Once placement of the Mini/Midi Ball-Type implant has been completed, the dentist can use one of the following techniques to place O-Ring Housings in a denture:

Laboratory pickup technique

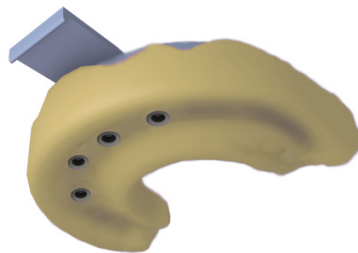
This technique is used for the fabrication of dentures in the laboratory:

- push the O-Ring Housings (with o-rings in place) onto the ball of each abutment/implant so that the o-ring is fully engaged on the ball (Fig 18);
- block the undercuts of the positioned O-Ring Housings with appropriate wax;
- take an impression over the O-Ring Housings in the usual way and allow the impression material to set;
- lift the impression tray off the implants: the O-Ring Housings will remain in the impression (Fig 19).

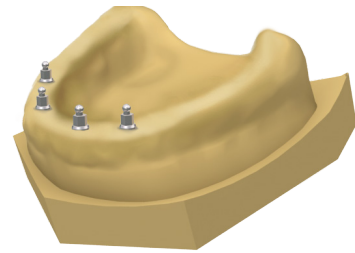
The impression, with O-Ring Housings in position, can be sent to the laboratory. The laboratory will create a model using the impression and Ball Implant Replicas and from this a denture is made for the patient (Fig 20). The denture is sent back to the dentist and fitted in the patient.



(Fig 18)



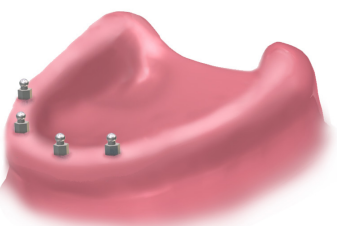
(Fig 19)



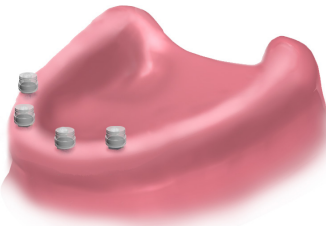
(Fig 20)

Chair-side pickup technique

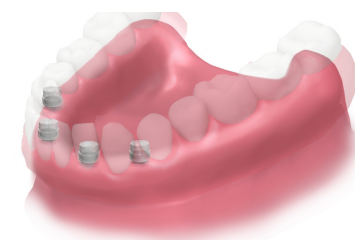
- For the placement of O-Ring Housings into a conventional denture (whether new or the patient's existing denture), the chair-side technique dispenses with the need for laboratory involvement post-surgery:
- cover the top of the balls with calcium hydroxide paste or indelible pencil (Fig 21), then push the denture onto them to mark the position for O-Ring Housings;
- hollow out the denture with a carbide bur at the newly-marked positions;
- fill the new hollows with self-cure acrylic resin;
- place the O-Ring Housings on the ball part of the implants and block the undercuts with wax, then firmly push the denture on to them by the patient biting down. (Fig 22)
- Get the patient to bite down on the denture once the resin has set remove the denture: the O-Ring Housings will be fixed into it. (Fig 23)



(Fig 21)



(Fig 22)

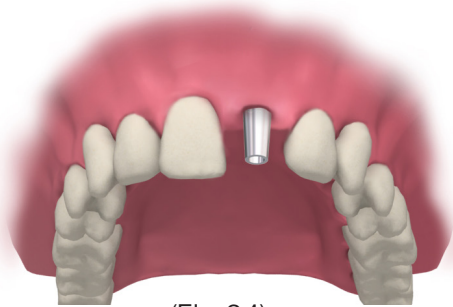


(Fig 23)

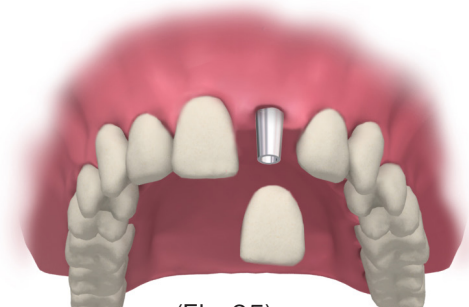
Restorative Phase

One-stage immediate functional Loading

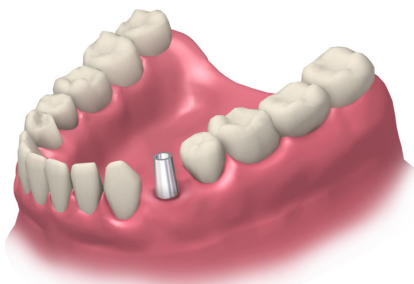
If the implant achieved good initial stability of 30Ncm as checked by the Torque Wrench, and if all the clinical factors prevail for immediate loading, the surgeon can choose the appropriate angle of the final abutment (whether SRA or SRBA) for an optimal emergence profile by using Trial Abutments. Once this angle is determined, the relevant final abutment is fixed to the implant by using the 1.5mm driver to drive in the Abutment Fastening Screw (AFS) (please refer to the AFS tightening procedure as set out below).



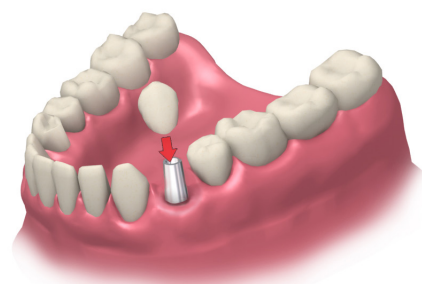
(Fig 24)



(Fig 25)

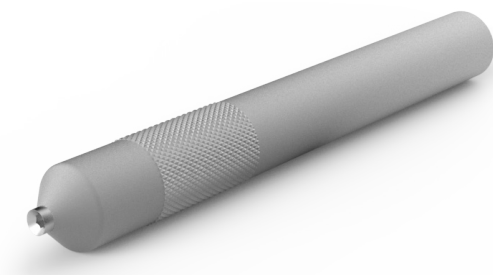


(Fig 26)



(Fig 27)

Abutment preparation (where necessary) can be performed intra-orally using sharp carbide burs with copious irrigation; alternatively it may be carried out chair-side by using the Abutment Preparation Handle (See Figs 28,29,30). The dentist will construct a temporary crown (please refer to the earlier section on the Restorative Phase).



(Fig 28)



(Fig 29)

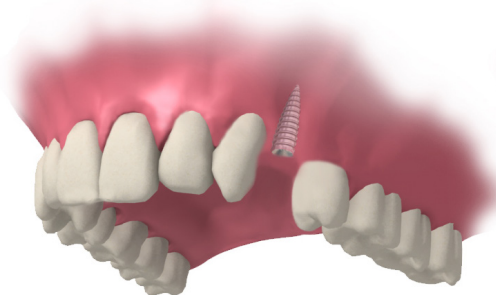


(Fig 30)

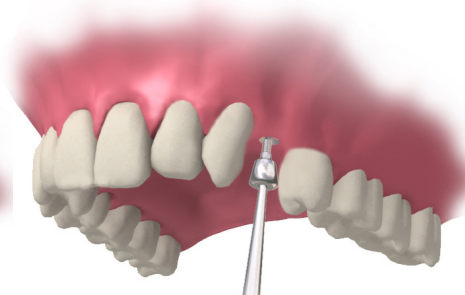
Restorative Phase

One-stage delayed function

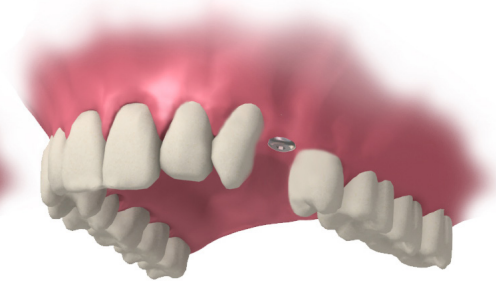
The clinician affixes a Healing Collar (available in different heights to suit the clinical situation) directly to the implant using the 1.5mm Hex Driver, and tightened to finger tightness, ensuring that the Healing Collar is fully seated upon the implant. The Healing Collar thereby contours and moulds the peri-implant soft tissue and second stage surgery is not required. This procedure could be used in a non-aesthetic zone such as for pre-molars and molars. After a few months of healing, the Healing Collar is removed and an impression is taken for the final restoration.



(Fig 31)



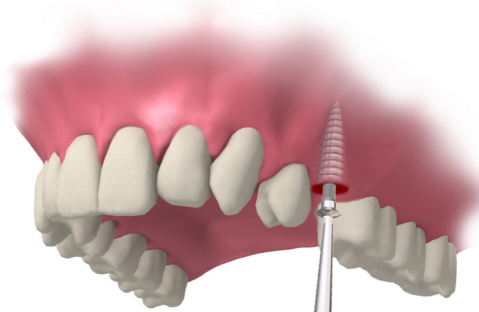
(Fig 32)



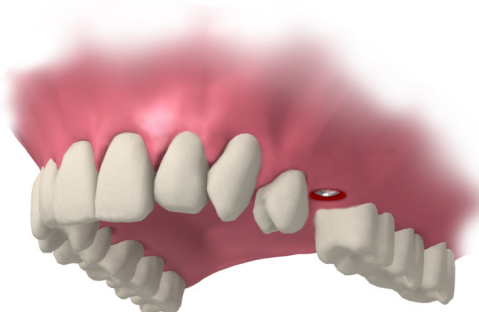
(Fig 33)

Two-stage delayed function

The Cover Screw is affixed to the implant following placement implant using the 1.5mm Hex Driver, and tightened to finger tightness, ensuring that the Cover Screw is fully seated upon the implant. The raised flap is sutured back over the top of the implant to allow for undisturbed healing. At second-stage surgery a soft tissue punch is used to uncover the implant after a healing period of three to four months, and the Cover Screw removed. A piezoelectric ultrasonic tip should be used to gently remove any bone growth over the Cover Screw. A Healing Collar is affixed to the implant (again, tightened to finger tightness) for 5 to 15 days to contour and mould the soft tissue. The relevant abutment can then be selected to achieve the desired aesthetic result, using Trial Abutments and abutment preparation as indicated above.



(Fig 36)



(Fig 37)



AFS tightening procedure

A number of studies have identified abutment screw loosening as a potential problem in two-piece restorations. This may result from micro-motions at the implant-abutment interface, bacterial ingress at the micro-gap, or simply a failure to screw in the fixation screw with the appropriate initial torque of 30Ncm (or more). While there have been very few instances of OsteoCare's AFS loosening in practice, the clinician should nevertheless adopt the following very simple steps to ensure appropriate initial torque: (1) tighten the AFS with the Ratchet; (2) check initial torque with the Torque Wrench; (3) wait 10 minutes for any "settling" to occur; (4) re-tighten the AFS with the Ratchet; (5) re-verify the torque with the Torque Wrench.

Notes

Treatment Philosophy

Any implant-based treatment should be made on the following basis in order to produce consistent and correct results:

- **patient assessment** - the suitability of patients for minor oral surgery must be established prior to implant treatment;
- **prosthetic parameters** - the form and position of the planned prosthesis must be established to fall within the aesthetic parameters;
- **surgical protocol** - implants should be placed anatomically ensuring that the implant site can be restored as planned;
- **restorative phase** - accurate and passively fitting restorations should be used to create the required aesthetics and occlusal form based on prosthetic parameters.

Patient assessment

Fitness for Surgery

A patient over 18 years of age who is well enough to undergo a minor surgical procedure (such as tooth extraction) is likely to be fit for implant treatment. There are few absolute contraindications, but each patient should be assessed by the clinician on a case-by-case basis.

When assessing a patient as a potential implant candidate, a number of factors must be evaluated: risks and contraindications, medical and dental history, the capability of implant therapy to resolve the patient's problem and dental suitability determined by examination.

Contraindications

Implant placement is contraindicated for patients who:

- are medically unfit for an oral surgical procedure, suffer serious internal medical problems, bone metabolism disturbances, uncontrolled bleeding disorders, inadequate wound healing capacity, poor oral hygiene, maxillary and mandibular growth not completed, poor general state of health, uncooperative or unmotivated patients, prolonged therapy-resistant functional disorders, xerostomia, weakened immune system, illnesses requiring periodic use of steroids, uncontrollable endocrine disorders;
- have inadequate bone volume unless an augmentation procedure can be considered;
- adequate sizes, numbers or desirable position of implants are not reachable to achieve safe support of functional or eventually parafunctional loads;
- smoke, have diabetes, or suffer from alcoholism, bruxism or psychological problems;
- are allergic or hypersensitive to titanium.

Notes

Extraoral examination

The value of replacing a particular tooth must be assessed in terms of its current and likely future usefulness. The predictability of dental implants means that there is now less value than before in “heroic intervention” such as repeated apicectomy procedures or constructing conventional bridgework on a non-vital abutment tooth.

In addition to the comprehensive examination given to any patient undergoing complex treatment, the position of the lip at rest and in extremes of movement must be noted, together with labial and buccal support provided by the patient’s natural teeth and/or current prosthesis. It is important to remember that edentulous patients may have lost considerable hard and soft tissue and that implant placement alone will not replace this tissue. If the lip-line is high, particularly during smiling, artificial gum or a longer than normal tooth using pink porcelain may be required to complete the aesthetics of the restorative process.

Intraoral examination

The intraoral examination links closely with radiographic analysis in providing an appraisal of the health and condition of the mouth and suitability for implant treatment. It is sensible to consider a “total care” approach to implant dentistry, looking especially at the value of treatment in preserving or improving the existing dentition. Active disease should first be treated and the clinician should be aware of the caries and periodontal status of any remaining teeth together with signs of parafunction or abnormality.

Prosthetic parameters - treatment planning

Treatment planning is the most important part of any prospective restoration. Correct and thorough planning involving the patient at certain stages provides a certain degree of comfort and confidence, and hugely reduces the possibility of problems arising during the restorative process. The clinician should make the most of tools available at his or her disposal, including:

- **discussion with the patient** - patient expectations should be assessed and noted, and managed where these are unrealistic. If the patient feels properly involved in the overall process then misunderstandings about treatment options are much less likely and any difficulties may be more easily overcome;
- **use of study models** - to visualise the intended outcome before commencing treatment, study models can be produced following a full clinical examination and discussed with the patient. These should provide very useful information about implant placement and any problems with occlusion;
- **wax-ups** - provide a “diagnostic simulation”. These can be used to assess ideal tooth position in relation to available bone and the smile line. Importantly, they provide both hard and soft tissue information - ideally implants will be placed in good quality bone surrounded by good, fixed, keratinised mucosa that is stable and will not move. Once an acceptable diagnostic set-up has been achieved it can be duplicated to provide a surgical guide to help position the implants correctly. Furthermore, the surgical guide can be constructed from the wax-up;

Notes

- **diagnostic imaging** - assists with the evaluation of any proposed implant site in terms of available bone, overlying soft tissues, inter-arch space, etc. Whilst much information can be gathered later from study models, more precise information on bone volume and density is essential. This can be obtained by conventional means, such as periapical radiographs, panoramic radiographs and lateral cephalographs. CBVT (Cone Beam Volumetric Tomography) has become the preferred tool for radiographic analysis in cases of multiple implant placements. Accurate information is provided on width, height, angulation and bone density;
- **diagnostic template** - the diagnostic template records the information regarding the teeth that are being replaced and is used at several different stages. Its purpose is to relate the position of the tooth to the underlying hard and soft tissues. It is constructed from the position of the teeth as determined by the diagnostic or the provisional restoration. It is hollow and forms a 'prosthetic envelope', which defines the labial and palatal surfaces of the desired crown as well as the gingival margin.

Surgical protocol

Implant placement surgery usually involves only minor preparation of the osteotomy and seating of the implant within this. Drilling guidelines, and instructions on implant placement, are provided in earlier sections of this Clinical Manual.

Paediatric Patients

The replacement of teeth by implants is generally restricted to patients with completed craniofacial growth. The placement of OsteoCare implants into patients whose craniofacial growth is incomplete is at the clinician's own risk.

Procedural Precautions

Surgical procedures

The risk of osseointegration failure increases as trauma to the osteotomy increases. Particular care should therefore be taken to eliminate sources of infection, contaminants, surgical and thermal trauma. All drilling procedures should be performed at 2000RPM or less, under continual, copious irrigation. All surgical instruments used must be in good condition, used in accordance with OsteoCare's instructions for use and good dental practice, and should be used carefully to avoid damage to implants or other components. Implants should be placed to ensure sufficient primary stability; however, excessive insertion torque may result in implant fracture, or fracture or necrosis of the implant site. The proper surgical protocol should be strictly adhered to.

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.

Notes

Cleaning and sterilisation

This section applies to:

- OsteoCare components which are delivered cleaned but not sterilised (whether single use only or for re-use)
- OsteoCare reusable instruments (eg, Burs, Drivers, Socket Formers, Ridge Expanders, etc);
- any other instruments to be used during surgery and for which there are no specific manufacturer's instructions relating to cleaning and sterilisation

Before EACH use, and subject to any modification operations to be performed at the laboratory and undertaken first, the item should be removed from any direct packaging, then cleaned, disinfected and sterilised as set out below.

Cleaning

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

- Items should be removed from any direct packaging or container, then cleaned (according to the manufacturer's instructions) using CE-marked detergent and/or disinfectant (pH 5 to 9) specific to the cleaning of medical devices;
- the Bur Cleaner should be used on any Universal Bur which has previously been used, following immersion of the Universal Bur in lukewarm detergent/disinfectant for at least 10 minutes. The Bur Cleaner should be inserted into the lumen with gentle pressure and rotated through a full revolution before removal, and then detergent/disinfectant solution should be squirted into the lumen using a syringe. This should be repeated as necessary;
- the use of a soft brush is recommended for removing external surgical debris;
- the use of an ultrasonic bath is recommended, with immersion in detergent according to the manufacturer's instructions;
- following cleaning and prior to sterilisation, items should be rinsed using distilled/deionised/purified/sterile water to remove the detergent/disinfectant;
- following cleaning and rinsing, items should be subjected to visual inspection to check for residual soiling.

Sterilisation

Components should be disassembled and then placed in a suitably-sized, sealable, porous paper autoclave pouch and sterilised using steam. Instruments in the Universal Surgical Kit or the Surgical Kit may remain in those kits for sterilisation purposes, since these are designed specifically to allow steam sterilisation.

We recommend a minimum temperature of 134°C for at least three minutes using an autoclave equipped for forced (vacuum) air removal. The use of a passive, gravity displacement autoclave (one without vacuum assisted air removal) is not recommended for wrapped (pouched) items or those with a lumen. The components should be allowed to cool to room temperature.

All surgical instruments must be sterilised before use to ensure that components remain sterile prior to placement

General Precautions

Procedural issues

Equipment/component verification

Please always verify IN ADVANCE OF SURGERY that you have all of the correct instruments available and the correct components (including making a visual check of an Implant and its specifications before removal from the sterile packaging), and that these are in suitable condition for use, including undertaking steps necessary for cleaning and sterilisation of instruments for the maintenance of hygiene standards during surgery

Insufficient number of implants

If the surgeon does not place sufficient dental implants to support biomechanical loads to be encountered by the relevant prosthesis, this may lead to mechanical failure of the prosthetic component which is used to support the prosthesis.

Undesirable positioning

If the surgeon has not placed dental implants in the correct position to support biomechanical loads to be encountered by the relevant prosthesis, this may lead to mechanical failure of the prosthetic component which is used to support the prosthesis.

Unsuitable implant

If the surgeon has placed an unsuitable implant, for example because it is not suited to the particular bone type or density, or is not of a requisite size to support the prosthetic component used (e.g. because the prosthetic component is highly angulated), then this may lead to mechanical failure of the prosthetic component which is used to support the relevant prosthesis.

Accordingly, dental implants need to be selected so that they provide an optimal connection and stability with the surrounding bone. OsteoCare dental implants are contraindicated where bone of insufficient quality or quantity is available to produce adequate stability and support.

Unsuitable Final Abutment

If the prosthetic component is placed upon the dental implant such that the angulation of prosthetic component is unsuited to support the relevant prosthesis; or the prosthetic component is the wrong size for the dental implant upon which it is placed, then this may lead to mechanical failure of the prosthetic component which is used to support the relevant prosthesis, or may lead to mechanical failure of the dental implant or fastening screw; it may also lead to damage to tissue surrounding the implant.

The design and construction of the abutment and prosthesis by the technician should incorporate appropriate retentive features for the prosthesis and should optimise the angulation between the implant fixtures and prosthesis such that applied loads are directed down the long axis of the implant. Failure to achieve this can lead to excessive bending force and fatigue failure of the implant components.

General Precautions

Insufficient torque

If the prosthetic component is not retained in the dental implant with sufficient torque on the fastening screw, then this may lead to mechanical failure of the fastening screw, prosthetic component or the dental implant; it may also or alternatively lead to loosening of the fastening screw or the prosthetic component and allow ingress of foreign material between the mating interfaces of the dental implant and the prosthetic component potentially leading to bacterial infection and damage to tissue.

Over-tightening

If too great a rotational force is applied to retain the prosthetic component in position, this may lead to mechanical failure of the fastening screw, prosthetic component or implant; it may damage the thread of the fastening screw, prosthetic component (where relevant) or dental implant; or it may cause damage to the surrounding bone and an increased risk of osseointegration failure.

Conclusions

Implant placement and prosthetic design must accommodate individual patient conditions such as bruxism or unfavourable jaw relationships to reduce the risk of overload or fatigue failure, and treatment is contraindicated if adequate accommodation cannot be accomplished. It is therefore essential that the clinician performs a complete assessment of the patient in advance of performing surgical and/or restorative procedures to minimise the risk of adverse events occurring.

The clinician must consult appropriate surgical and restorative manuals and textbooks for information on treatment planning and medical evaluation to ensure appropriate planning, design and construction for placement of the implant, prosthetic component and prosthesis. Please contact OsteoCare if you have any doubts.

The System has specific design characteristics for mating OsteoCare components such as implants, abutments and prosthetic components. Combining components that are not configured or dimensioned for correct mating, or seeking to combine OsteoCare components with components from different implant systems, can lead to the problems indicated above including mechanical failure of components, osseointegration failure or unsatisfactory aesthetic results. This would also void the OsteoCare warranty.

Adverse effects

Implant placement techniques have normal contraindications and risks, including those identified in section 6 above. These are extensively documented in the dental literature. Incorrect clinical placement or loading resulting in loss of implant anchoring or loss of the prosthesis are possible events after surgery. Lack of bone quantity or quality, infections, poor patient hygiene or cooperation, and general diseases are some potential causes for loss of anchoring and function.

Sterility

All OsteoCare dental implants are supplied sterile with a given expiry date as indicated by the packaging. Upon expiry, dental implants should be discarded. For re-sterilisation of non-sterile components (where appropriate), please refer to the IFU for Re-Useable Instruments & Prosthetic Components.

General Precautions

Warranty

OsteoCare offers a lifetime warranty (i.e. up to the indicated expiry date or utilisation quota of the relevant component/instrument) on its products. For full terms and conditions please refer to the warranty section of our website at www.osteocare.uk.com

Disclaimer of liability

OsteoCare guidelines or clinical documents (including but not limited to Instructions for Use) are not adequate to allow inexperienced clinicians to administer professional implant treatment or prosthetic dentistry, and are not intended to substitute for formal clinical or laboratory training. The use of OsteoCare products should only be used by individuals with training and experience specific to their clinically accepted application.

Warnings

Some OsteoCare products are labelled “Single Use Only”, including in particular dental implants, SRAs and Final Abutments. Such components are specifically intended to be used only once in order to avoid significant risks associated with reuse. Those risks include product contamination, patient infection and/or failure of the device to perform as intended. Accordingly, the reuse of OsteoCare products which are labelled “Single Use Only” is entirely at the clinician’s own risk.

OsteoCare implants which are contaminated by surface contact are therefore no longer sterile. In those circumstances, the implant must be discarded.

Similarly, if the package has been damaged or previously opened, the relevant component should be returned to OsteoCare for replacement to avoid the use of a potentially contaminated product and its attendant risks as highlighted immediately above

The use of OsteoCare products with components manufactured by third parties for which, they were not designed, may invalidate the guarantees and other expressed obligations of OsteoCare.

Surgical

Surgical and restorative products used to achieve and maintain osseointegration (i.e. the direct structural and functional connection of the surface of the implant to the jaw bone to ensure the mechanical stability of the implant) should be utilised by persons trained in this method. Such training is offered by OsteoCare.

Pre-operative patient evaluation and close cooperation between surgeon, restorative dentist and dental laboratory technician are essential for success.

MR Conditional

OsteoCare dental implants are described as MR Conditional, namely, “an item with demonstrated safety in the MR environment within defined conditions”. OsteoCare dental implants and prosthetic components have not been evaluated for safety and compatibility in the MR environment, including in relation to heating or migration in the MR environment. Nevertheless, research has demonstrated that titanium and titanium alloy (6Al-4V) implants and components can be used for imaging in conventional MRI machines using 3T magnetic fields, as well as being safe for imaging in ultrahigh field MRI machines at 7T using the following sequences: 2D-SE (Spin Echo) T1-weighted images; 2D SE T2-weighted images; 3D FSE (Fast SE) T1-weighted images; 3D-FSE T2-weighted images; 3D gradient echo (GRE) T1-weighted images using a spoiled gradient recalled acquisition in the steady state (SPGR) technique; and 3D-GRE T2/T1- weighted images using a fast imaging technique employing steady state acquisition (FIESTA). Such devices also have a history of safe use with magnetic fields during MRI. OsteoCare dental implants are made of titanium alloy 6Al-4V.

The clinician’s attention is therefore drawn to the possible effects of MRI of dental implants and abutments, as well as to the well-known effects that titanium implants have in producing artefacts in radiographic images produced by MRI.

General Precautions

Monitoring and Maintenance

After successful placement of implants, verify primary stability and appropriate occlusal loading before proceeding with the placement of the provisional or permanent prosthesis. The monitoring of patients should follow the protocol outlined below:

Time from surgical/restorative procedure	Assessment
1 week	Clinical Assessment Baseline Radiographs
1 month	Clinical Assessment
3 months	Clinical Assessment Oral Hygiene Instructions
6 months	Clinical Assessment Radiographs Oral Hygiene Instructions
12 months	Clinical Assessment Radiographs Oral Hygiene Instructions
18 months	Clinical Assessment Radiographs Oral Hygiene Instructions
24 months	Clinical Assessment Radiographs Oral Hygiene Instructions
Annually thereafter	Radiographs

Clinical Assessment

1. Visual examination
2. Percussion
3. Probing
4. Occlusal examination (central relation & lateral excursions)
5. Patient Feedback

Radiographic Examination

1. Periapical radiographs taken using long cone technique and the “Rinn” paralleling system.
2. OPG – to assess bone levels in situations where periapical radiographs do not provide an accurate result.

Oral Hygiene

Oral hygiene instructions should be given in order to ensure that a plaque-free environment is maintained. Use of dental floss, inter-dental brushes, superfloss and single tufted brushes should be recommended as access allows.

Incident Reporting













Adverse incidents involving OsteoCare products should be reported to OsteoCare using the contact information provided below. Serious adverse incidents must be also be reported to your national competent authority.

info@osteocare.uk.com

+44 (0) 1753 770006

General Precautions

Symbols

Symbol	Explanatory Text
	Authorised representative in the European Community
	Manufacturer's catalogue reference which uniquely identifies the medical device model.
	Indicates a medical devices has been sterilised using irradiation.
	Single use only.
	Indicates the need for the user to consult the instructions for use for important cautionary warnings and precautions that cannot , for a variety of reasons, be presented on the medical device itself.
	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Indicates the date when the medical device was manufactured.
	Indicates the date after which the medical device is not to be used.
	Indicates the name and address of the manufacturer.
	Do not use if the package has been damaged or previously opened.
	The symbol applied to products to indicate that they conform with relevant EU directives regarding health and safety or environmental protection.
	To indicate that the device that is normally provided sterile in the same packaging or similar packaging has not been sterilised.

References

Gapski, R., Wang, H., Mascarenhas, P. and Lang, N. (2003). Critical review of immediate implant loading. *Clinical Oral Implants Research*, 14(5), pp.515-527.

See, e.g., Oriso et al. Impact of Static and Radiofrequency Magnetic Fields Produced by a 7T MR Imager on Metallic Dental Materials, *Magn Reson Med Sci*. 2016;15(1):26-33.

To Order:

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Website: www.osteocare.uk.com

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NB: OsteoCare reserves all rights to change, modify and improve specifications of, or discontinue products at any time.

OsteoCare strongly recommends that all users of its system should acquire specialist training before undertaking any of the clinical procedures. OsteoCare provides training appropriate for various levels of knowledge. For more information please contact OsteoCare.

Some products may not be available in all markets.