Reusable instruments instructions for use

These Instructions for Use (IFU) cover the following OsteoCare reusable instruments (the "**OC Reusable Instruments**") which form part of the Universal Surgical Kit or which may be supplied individually:

- Drivers, Handpiece Drivers, and Torque Wrench Connectors
- Osteotomy Probe
- Trial Abutments
- Socket Formers
- Ridge Expanders
- Centre Finder

The following reusable instruments also form part of the Universal Surgical Kit, but are not manufactured by OsteoCare ("**Other RIs**"). Instructions for use (where relevant) for the Other RIs are included in paper form inside the Universal Surgical Kit.

- Ratchet
- Torque Wrench
- Titanium Tweezers
- Surgical Mallet

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

The OC Reusable Instruments are for use only with OsteoCare dental implants and/or other OsteoCare components for which they are designed, unless otherwise stated.

Reprocessing of the OC Reusable Instruments and Other RIs must be performed in accordance with the requirements of section 4 (*Cleaning and sterilisation*) below.

(1)  (2)  (3)  (4)  (5) 	Please refer to the packaging and label of your device to identify the details (range and size) of the medical device to be used. Also to be found on the packaging and label, are provided (each beside the relevant standard symbol reproduced here for convenience): (1) confirmation that the item is a medical device; (2) lot number; (3) date of manufacture; and (4) catalogue reference of the device, each beside the standard symbols reproduced here for convenience. (5) caution (in relation to the sharp point of Site Markers and Pilot Socket Formers). Please also refer to section 11 (*Warnings*) below, which identifies further symbols included on the packaging.
	**OC Reusable Instruments and Other RIs are provided non-sterile.**

Please always verify IN ADVANCE OF SURGERY that you:

- **perform adequate planning steps;**
- **have all of the correct instruments and components available;**
- **confirm instruments and components are in suitable condition for use;**

- **perform cleaning and sterilisation of OsteoCare prosthetic components, OC Reusable Instruments, and Other RIs for the maintenance of hygiene standards during surgery, in accordance with the procedure described in section 4 (*Cleaning and sterilisation*) below.**

1. BASIC UDI-DI

The Basic UDI-DI (and product code) for the above-listed components is as follows:

Basic UDI-DI	Component name	Product code
506091295Drivers1HF	Drivers	IN-[Y]HD-[XXX] IN-OHD[Y]-[XXX] IN-RCD[Y]-[XXX] IN-RCBD-150
	Handpiece Drivers	IN-BP[Y]-[XXX]
	Torque Wrench Connectors	IN-TRC-01[Y]
506091295TrialTQ	Trial Abutments	IN-TA3-0[XX]
506091295CentreXW	Centre Finder	IN-CTF-001
506091295Reuse1rPC	Osteotomy Probe	IN-OSP-001
	Socket Former	IN-ISF[Y]-[XXX]
	Ridge Expanders	IN-RDE-00[X]
Not applicable (these are not medical devices for which OsteoCare is the manufacturer)	Ratchet	IN-RAT-220
	Torque Wrench	IN-TRW-001
	Titanium Tweezers	IN-TTW-001
	Surgical mallet	IN-SMA-001

2. PRODUCT PACKAGING

OC Reusable Instruments and Other RIs are supplied either: (1) as non-sterile in the form of a kit (Universal Surgical Kit or Surgical Kit); (2) in a tamper-proof blister pack for smaller components purchased individually; (3) as part of a kit (for Socket Formers and Ridge Expanders); or (4) individually and safely wrapped for larger reusable instruments purchased individually. If the clinician receives a reusable instrument which appears damaged, please return the same to OsteoCare for replacement.

3. DESCRIPTION AND INTENDED USE

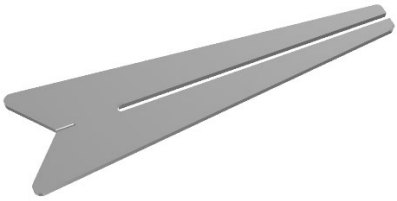
3.1 Materials

The OC Reusable Instruments are made of titanium alloy 6Al-4V ELI (Socket Formers, Trial Abutments, Osteotomy Probe, Long-Handled Drivers, Ratchet-Connected Drivers), or stainless steel (Handpiece Drivers, Torque Wrench Connectors, Ratchet-Connected Over-Hex Drivers, Ratchet-Connected Ball Driver, Centre Finder, Ridge Expanders, tips of Site Marker and Pilot Socket Former).

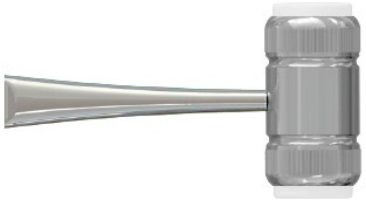
3.2 Intended use and clinical benefits

Drivers and Torque Wrench Connectors Drivers and Torque Wrench Connectors have a square interface allowing a precision connection to the Ratchet or Torque Wrench, as desired. Other than the long-handled drivers, the square interface includes a rubber O-ring (which may be easily replaced) to ensure that the driver remains in position. Handpiece Drivers have an interface for connecting to a Type 1 dental handpiece	
	**1.9mm Over-Hex Driver (Long or Short)** comprises a 1.9mm (across flats) internal hex for the placement of Mini Implants; **2.4mm Over-Hex Driver (Long or Short)** comprises a 2.4mm (across flats) internal hex for the placement of Midi Implants and Maxi Z One-Piece Implants.

	**1.5mm Hex Driver** comprises a 1.5mm (across flats) external hexagon for engaging with the internal hexagon of Cover Screws, Abutment Fastening Screws, Healing Collars and Impression Transfers; **2.2mm Hex Driver (Extra Long, Long, or Short)** comprises a 2.2mm (across flats) external hexagon for engaging with the internal hexagon of all OsteoCare two-piece implants. The Long and Extra Long 2.2mm Hex Drivers include an engraved ring 2mm back from the hexagonal driving tip for the clinician to judge implant depth during flapless surgery: where the ring is level with the gingiva, the implant will be positioned approximately equicrestally to the peri-implant bone.
	**1.9mm Bur Handpiece Over-Hex Driver** connects to a dental handpiece and comprises a 1.9mm (across flats) internal hex for the placement only of **Mini Implants**; **2.4mm Bur Handpiece Over-Hex Driver** connects to a dental handpiece and comprises a 1.9mm (across flats) internal hex for the placement of **Midi Implants** and **Maxi Z One-Piece Implants**.
	**1.5mm Bur Handpiece Hex Driver** connects to a dental handpiece and comprises a 1.5mm (across flats) external hex for engaging with the internal hexagon of Cover Screws, Abutment Fastening Screws, Healing Collars and Impression Transfers; **2.2mm Bur Handpiece Hex Driver** connects to a dental handpiece and comprises a 2.2mm (across flats) external hex for engaging with the internal hexagon of all OsteoCare two-piece implants.
	**1.5mm Ratchet-Connected Ball Driver** comprises a "balled" 1.5mm external hexagon for use in particular during insertion of Abutment Fastening Screws (AFS) for affixing an abutment to an OsteoCare implant. The *ball* profile of the hexagon allows fixation of the AFS where structures in the mouth prevent use of the conventional 1.5mm Hex Driver: the *ball* allows angular correction of up to 20 degrees.
	**Long-handled 1.5mm Hex Driver** is 160mm long, with a 1.5mm (across flats) external hexagon for engaging with the internal hexagon of Cover Screws, Abutments Fastening Screws, Healing Collars and Impression Transfers in situations where enhanced manual control is desired; **Long-handled 2.2mm Hex Driver** is 160mm long, with a 2.2mm (across flats) external hexagon for engaging with the internal hexagon of all OsteoCare two-piece implants, with enhanced control during placement of implants in particular in the upper anterior region.
	**1.5mm Torque Wrench Connector (Long or Short)** comprises a 1.5mm (across flats) external hexagon specifically for use with the Torque Wrench to allow precise affixing to a torque of 30 Ncm of OsteoCare abutments to OsteoCare implants using Abutment Fastening Screws.
Other OC Reusable Instruments The use of Socket Formers and Ridge Expanders involves advanced techniques which should not be attempted by inexperienced clinicians without first attending appropriate training courses.	
	**Osteotomy Probe** – the probe (with a 1.25mm diameter ball tip) is used to verify the depth of a prepared osteotomy or extraction socket, with graduations at 2.0mm intervals.

	**Trial Abutments** – angulated from 0 to 45 degrees, in 5 -degree increments, and with a 2.2mm external hex which engages all two-piece implants. This ensures that the clinician can accurately assess the insertion angle of the implant (ie, the angle between the implant axis and the normal to the occlusal plane) to ensure the ideal restoration.
	**Socket Formers** – (Site Marker, Pilot Socket Former, and 3.0, 3.75, 4.5 and 5.5mm (pointed or flat-end Socket Formers)) are for osteotomy preparation in low-density bone, and may also be used to condense peri-implant bone for enhanced primary stability of the implant. Flat-End Socket Formers may also be used for internal sinus lifting and for expansion of narrow alveolar ridges, each using the Surgical Mallet. Graduations are marked at 10.0mm, 12.0mm, 14.0mm, 16.0mm, 18.0mm, and 20.0mm from the tip.
	**Ridge Expanders** – for use with the Surgical Mallet in increasing the width of available bone in narrow maxillary ridges, including by separation of the cortical plate for inter-positional grafting. The “D”-shaped cross-section of the cutting tip allows penetration into the bone while preventing buccal fracture and retaining the necessary strength. Graduations are marked at 10.0mm, 15.0mm and 20.0mm from the tip.
	**Centre Finder** – in edentulous sites (usually limited to a single tooth), the Centre Finder will allow precise identification of the centre of the gap using a scalpel or Site Marker and precise measurement of the mesiodistal gap.

The Other RIs comprise the following:

	**Ratchet** – for connection to any Drivers for placement of OsteoCare implants and associated components such as a Screw-Retained Abutment.
	**Surgical Mallet** – for use with Socket Formers and Ridge Expanders as indicated above.
	**Titanium Tweezers** – for careful handling of equipment while maintaining appropriate cleanliness and sterility during delicate procedures, as well as for manipulation of OsteoCare dental implants without damaging their surfaces.

	**Torque Wrench** – for connection with Hex or Over-Hex Drivers to verify primary stability of placed OsteoCare implants; or for affixing OsteoCare abutments to implants using Abutment Fastening Screws tightened to the requisite 30 Ncm torque.

Please refer to the individual instructions for use supplied with or available for (eg, electronically) the Other RIs for detailed explanations relating to those instruments.

4. CLEANING AND STERILISATION

OC Reusable Instruments and Other RIs, whether provided as part of the Surgical Kit, or a Socket Former or Ridge Expander Kit, or individually, are delivered decontaminated but **non-sterile**. **All surgical instruments must be cleaned, disinfected, and sterilised before surgery to minimise the risk of bacterial and/or viral infection from contaminated instruments.**

OC Reusable Instruments and Other Ris may be cleaned by one of two validated methods – a manual cleaning procedure (section 4.4 below), or an automated cleaning procedure (section 4.3 below) using an automated washer-disinfector which meets the requirements of ISO 15883. In each case, **the instruments must be removed from any kit box/tray** (eg, the Universal Surgical Kit box/tray) **and cleaned individually**, and the instrument tray must be removed from the container and each of the tray and container must be cleaned separately.

The reprocessing steps provided below have been validated for preparing the OC Reusable Instruments and Other RIs for reuse according to the requirements of ISO 15883 (for cleaning) and ISO 17665 (sterilisation), to reach a sterility assurance level (SAL) of 10^{-6}.

It is the responsibility of the processor (ie, the person(s) performing or overseeing the steps described in this section) to ensure that the processing is performed using equipment, materials, and personnel in the processing facility, which/who are suitable for ensuring that the reprocessing is effective.

Warning: do not deviate from the steps set out in this section.

4.1 Initial treatment at point of use (prior to reprocessing)

Before and during clinical procedures

- The clinician must inspect all instruments and components to be used in a clinical procedure to determine if there is any damage, wear, and/or residual soiling.
- If at any time (including during clinical procedures) the clinician determines that an instrument is obviously worn or no longer able to fulfil its intended purpose due to damage, it should be discarded immediately in dedicated disposal containers to prevent reuse.
- During clinical procedures, the clinician should return reusable instruments and reusable surgical instruments to the designated position in the relevant kit for ease of use and to reduce the risk of injury and cross-infection.

After clinical procedures

OsteoCare recommends that the processor performs the steps set out below while wearing suitable clean protective clothing and equipment.

Remove gross soiling	• As soon as possible following the clinical procedure – where possible before the soiling dries, the processor should remove as much of this as possible from instruments using wipes and/or a soft brush and running water. • For Universal Burs, the Bur Cleaner should be used to remove debris from the internal lumen, in accordance with the steps described in the *Manual cleaning* sub-section below. • Heavy soiling/dried soiling should be treated by soaking the soiled instrument in 0.4% Triple-Zyme solution at between 27 and 35 degrees centigrade for at least 30 minutes.
Containment for safe transportation	• If instruments are not to be cleaned immediately (OsteoCare recommends immediate cleaning), they should be stored in a clearly-marked puncture-proof container in quarantine conditions to avoid any risk of use without cleaning and sterilisation, and to prevent any risk of injury and cross-infection to the clinician and clinical staff.

4.2 Preparation before cleaning

Disassembly	• Remove the item from direct packaging. Where part of a kit, remove the instrument from the kit in advance of cleaning. • The Titanium Tweezers supplied as part of the Universal Surgical Kit may assist the processor in handling small components. • The Torque Wrench (IT-TRW-001) must be put into the "broken" position for cleaning (ie, where the applied torque exceeds 30 Ncm).
Sonication	• Before cleaning, submerge the instruments in an ultrasonic bath with 0.5% detergent solution and process for 10 minutes. • **Warning:** Do not allow the instrument to rest on the bottom of the ultrasonic cleaner. • Flush the inner lumens, channels, and cavities of all visible soil using cold tap water for at least 10 seconds.

4.3 Automated cleaning

The Getinge Ultra 810 LX washer disinfector was used during the validation process for the automated cleaning steps described in this section.

Preparation	<u>Individual components or small instruments</u> • To prevent the loss of small devices, we recommended to contain them in a manner that allows them to be held securely and still permit full exposure to all cleaning surfaces. <u>Kits</u> • Instruments which are part of a kit should be removed from the inserts in the instrument tray and may be placed individually into the washer-disinfector, or placed into a DIN-style tray/basket, taking into account always (see "caution" section below) that: (1) some instruments have very sharp points and/or cutting edges; and (2) instruments made of different metallic materials must not be allowed to touch during the cleaning phase. Please refer to the table below on items that may be grouped together. • For the Universal Surgical Kit, remove the titanium sample dish (the round dish, approximately 3cm diameter) from the instrument tray for this to be washed separately from the instrument tray. Then remove the instrument tray by inserting a finger into the hole in which the sample dish was placed and lifting this gently out. • The Universal Surgical Kit box should be placed in the washer in the "fully open" position. • Ensure that the devices are positioned so that cavities (such as the sockets of Over-Hex Drivers) and lumens (ie, of Universal Burs) are unobstructed. **Caution** • Ultra Pilot Burs, Ultra Profile Burs, Pilot Socket Formers, and Site Markers each have an extremely sharp point; all Burs have sharp cutting edges. The processor must pay particular attention to the risks of sharps injuries from these instruments and ensure appropriate safety measures are in place. • Items made of different materials should be kept separate to avoid the risk of galvanic corrosion. For ease of reference, the materials for relevant components and instruments are set out below.
	Stainless steel: Universal Surgical Kit instrument tray, Socket Former Kit or Ridge Expander Kit cassettes, STS Burs, Ultra Profile Bur, Ultra Pilot Bur, Ultra Stop Bur, Over Hex Drivers, Torque Wrench, Torque Wrench Connectors, Ratchet, Bur Extender, Ridge Expanders, Ratchet-Connected Ball Driver **Titanium/titanium alloy**: Universal Burs, Universal Surgical Kit sample dish, Titanium Tweezers, Long-Handled Drivers, Hex Drivers, Trial Abutments, Impression Transfers (screws and copings), Abutment Fastening Screws, Healing Collars, Cover Screws, Screw-Retained Abutment, One-Piece Ball Attachment, Screw-Retained Ball Attachment, Osteotomy Probe, Titanium Guide Tubes, Socket Former, Bur Cleaner, Handpiece Driver **Other**: Bridge Cast Gold Abutment, Direct Cast Gold Abutment
Conditions for automated washing (reference to *tap water* is to the water ordinarily supplied	Automated cleaning will be performed as follows: • One pre-wash stage with tap water at <40 °C for 1 minute. • One wash stage with a solution of 0.4% solution of enzymatic detergent (eg, Triple-Zyme) in tap water at >50 °C for 4 minutes.

into the automated washer-disinfector used during processing)	• One rinse cycle at >40 °C for 1 minute using tap water.
Disinfection	One disinfection cycle at 90 °C for 1 minute, using purified water.
Drying	Dry the instruments/components at a minimum 70°C for 10 minutes.

4.4 Manual cleaning

Preparation	OsteoCare recommends that the steps set out below are performed while wearing suitable clean protective clothing and equipment. OsteoCare recommends that manual cleaning steps requiring a detergent are performed with an enzymatic cleaner such as Triple Zyme. The processor must identify and comply with the instructions for use for the enzymatic cleaner, noting in particular the optimal temperature for use and the concentration requirements.
Accessories	The processor uses the Bur Cleaner to remove surgical debris from the lumen of the Universal Bur (see section 4.1 (*Initial treatment at the point of use*) above). The Bur Cleaner must therefore also be cleaned in accordance with this sub-section.
Conditions for manual clean	Manual cleaning will be performed using a double container setup (one for cleaning and one for rinsing) paying special attention to Universal Burs, lumens, and cavities according to the following cleaning procedure: Note: The Bur Cleaner is a cleaning accessory and will be processed following the same procedure after use. Note: kit containers (boxes/trays/cassettes) must be disassembled, and the parts cleaned separately. **Wash Stage:** • One wash stage at < 35 °C for a minimum of 1 minute. Keeping the instruments submerged within a solution of 0.4% Triple Zyme detergent in distilled water. While brushing with an autoclavable brush, the technician cleaning the instruments will ensure cleaning solution is applied to all surfaces of the medical device until all visible soil is removed. For Universal Burs only (which may form part of a Universal Surgical Kit, and for which this part is copied from TD-IFU-04 (*Burs instructions for use*) for ease of reference): 1. Insert the Bur Cleaner as far as it will go into the irrigation channel, rotating it through a full revolution when fully inserted. 2. Remove the Bur Cleaner and flush the irrigation channel with an appropriate syringe filled with fresh detergent solution. 3. Repeat steps 1 and 2 on each Universal Bur for a total of three times. For other devices with lumens and cavities: • Flush the lumen or cavity with an appropriate syringe filled with fresh detergent solution and brush with a small soft nylon brush. **Rinse Stage:** • One rinse stage at <35 °C for 1 min. Using 500 mL distilled water. Performed within a separate sink/container.
Drying	• Items should be allowed to dry naturally in a clean environment until visibly dry. • Items may alternatively be dried using compressed air in position in a kit (so that they are held in position in the kit using the silicone inserts). For small individual components, compressed air should only be used where the component is held securely immobile.

4.5 Post-cleaning steps

Maintenance and inspection	All instruments must be inspected for wear or other signs of physical damage, or residual soiling. The processor should pay particular attention to: • lumens of Universal Burs and socket cavities of Over-Hex Drivers for residual soiling; • cutting tips and faces of drills (ie, Universal Burs, Ultra Burs) for signs of wear and other physical damage.
Repackaging	Any instruments which are part of a kit should be replaced into their position in the relevant kit prior to sterilisation. The Torque Wrench should be returned to the “unbroken” position.

	For the Universal Surgical Kit, replace the instrument tray into the Universal Surgical Kit box, and replace the titanium sample dish into the round hole therefor. **Caution** When placing the instrument tray into the Universal Surgical Kit box, or when handling any a Socket Former Kit, Drill Kit, or Drill Stop Kit, the processor must pay particular attention to the position of Instruments which represent a sharps risk (eg, Ultra Burs, Ultra Pilot Burs, Pilot Socket Formers, and Site Markers) to reduce the risk of sharps injuries.

4.6 Sterilisation

The Systec VX-120 autoclave was used during the validation process for the sterilisation steps described in this section.

Equipment	• For a kit, the kit should be placed into a sterilisation pouch which is suitable for steam sterilisation at 134 degrees centigrade, with all items in position in the kit. • Individual components or instruments should be placed into a suitably-sized sterilisation pouch. Recommended sterilisation pouches include (without limitation) Qualitix® sterilisation pouches (manufactured by Socorex Isba SA) – single-use pouches with self-sealing strip and a PET/CPP transparent laminated film to provide visibility of the contents of the pouch.
Steam sterilisation cycle	Three minutes at 134 degrees centigrade.

4.7 Post-sterilisation

Storage	• Where the processor sterilises items without intending to use them immediately, store the sterilised items in the sterilisation pouch under the conditions stipulated by the instructions for use of the sterilisation pouch. • Ensure that the place of storage is clearly marked as containing sterile instruments and that the expiry date of sterilisation is provided with the sterilisation pouch.

4.8 Manufacturer contact

Please refer to the contact information provided at section 15 (*Manufacturer and EU authorised representative*) of these instructions for use.

5. INDICATIONS FOR USE

OC Reusable Instruments are for use in the preparation and placement only of OsteoCare dental implants and prosthetic components.

5.1 Drivers and connectors

Drivers and connectors are indicated only for use with OsteoCare implants and associated prosthetic and restorative components. In particular, they are indicated for insertion or removal of OsteoCare implants, abutment fastening screws, cover screws, and healing collars. The clinician may provide the torque for insertion/removal using (1) fingers; (2) the Ratchet; or (3) the Torque Wrench – which provides a means for more accurate control of the insertion torque specifically in relation to manual insertion of Abutment Fastening Screws.

The clinician should perform a visual inspection of a driver or connector (as appropriate) following use for any signs of wear – in particular checking for rounding of the hexagonal driving tip on Hex Drivers; and any signs of fatigue damage – for example, plastic deformation of a tip or the appearance of small cracks or chips. Where such damage is present, **the driver/connector must not be reused**.

1.5mm Hex Driver and the 1.5mm Long-Handled Driver must not be used with the Torque Wrench to insert Abutment Fastening Screws to the requisite fastening torque (30 Ncm), as the hexagonal tips are designed only for low insertion torques and may deform or shear off at high torques. Only the Torque Wrench Connectors and the Ratchet-Connected Ball Driver (where accessibility is more restricted) should be used with the Torque Wrench.

5.2 Handpiece Drivers

Handpiece Drivers are also indicated only for use with OsteoCare implants and associated prosthetic and restorative components and carry out similar functions as other OsteoCare drivers, albeit that their use is more limited, in particular to ensure adequate control during implant placement. For this purpose, the osteotomy should first be prepared by sequential drilling (it is not recommended for single-drill scenarios). The clinician then inserts the implant with his/her/their fingers turning the PEEK carrier cap until further insertion is difficult.

The relevant Handpiece Driver is then inserted into the dental handpiece, the clinician first performing a visual inspection of the driver's shank and the handpiece chuck to ensure that there is no damage or debris that would affect the connection or the driver's operation. The dental handpiece should only be used at low speed settings (eg, 50rpm) and with appropriate torque control applied – which is to say, at least 30 Ncm for implants, 30 Ncm for affixing final abutments and PEEK Temporary Abutments using Abutment Fastening Screws (AFSs); and 5 to 10 Ncm for Healing Collars and Cover Screws. If the handpiece does not have torque control, it should not be used to fully insert a component; rather, the final insertion should be performed using the relevant driver and Ratchet and/or Torque Wrench.

5.3 Socket Formers

Socket Formers are indicated for:

- the preparation of an osteotomy for implant placement in low density bone;
- the expansion of atrophic ridges;
- for condensing poor quality bone to increase bone density.

Flat-end Socket Formers are also indicated for use with a surgical mallet for internal sinus floor augmentation to increase available bone volume below the maxillary sinus.

Circumferential grooves at 10.0mm, 12.0mm, 14.0mm, 16.0mm, 18.0mm, and 20.0mm enable the clinician to determine the depth to which a Socket Former has been inserted into the jawbone.

5.4 Ridge Expanders

Ridge Expanders are indicated for use with a surgical mallet for expansion of atrophic ridges, in particular the maxillary ridge. The "D"-shaped cross-section of the ridge expander allows expansion of the bone buccally.

The use of Socket Formers and Ridge Expanders are advanced surgical techniques which should not be performed by a clinician without adequate training in those techniques.

Graduations marked at 10.0mm, 15.0mm, and 20.0mm enable the clinician to determine roughly the depth to which a Ridge Expander has been driven into the jawbone.

5.5 Osteotomy Probe

The Osteotomy Probe is indicated for determining depth and integrity of the implant bed. The first circumferential groove behind the probe tip is at 2.0mm, the second at 4.0mm, and so on at 2.0mm intervals up to 20.0mm back from the tip. The grooves at 10.0mm and 20.0mm are more pronounced for the clinician to more easily determine the groove position.

5.6 Trial Abutments

Trial abutments are indicated for use during the restoration phase of implant treatment to determine the insertion angle of the implant and during surgical placement of an implant to check the implant's position and orientation.

5.7 Centre Finder

The Centre Finder is indicated for finding the central osteotomy preparation site in bounded areas (ie, areas in which there is a single- or double-gap). It has a measurement function which allows the width of the gap to be determined, and a central slit which allows the clinician to mark the central line between teeth using a scalpel or tissue marker.

6. SURGICAL PROCEDURES

For a detailed explanation of procedures for the use OC Reusable Instruments and Other RIs, please refer to the Clinical Manual.

6.1 Planning

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

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

The clinician must also be aware of the position of sensitive anatomical structures in the patient's mouth to minimise the risk of damage to the same from drilling and/or other surgical procedures such as implant insertion, ridge expansion, and sinus lifts.

6.2 Surgery

Surgery should only be performed in a clean, controlled environment suitable for surgery and with all of the equipment necessary or which it is reasonably foreseeable will be required during surgery. Such equipment should be in good condition and sterilised as necessary.

Some OC Reusable Instruments are small and present a risk of swallowing or aspiration. The clinician should take appropriate steps during treatment to protect patients as a means of preventing swallowing or aspiration[1].

The clinician must avoid applying excessive force to the dental implant – including in the use of Drivers and Torque Wrench Connectors during insertion.

7. RESTORATIVE PROCEDURES

7.1 Post-surgery

The healing period varies depending on the quality of the bone at the implantation site, the tissue response to the implanted device and the surgeon's evaluation of the patient's general health as well as the bone density at the time of the surgical procedure. Excessive force applied to the dental implant should also be avoided during the healing period. Proper occlusion should be evaluated on the prosthetic restoration to avoid excessive force.

7.2 Trial Abutments

The intended purpose of Trial Abutments is to provide a means of identifying a non-ideal insertion angle so that the clinician can correct this during the restoration phase.

The clinician first places a 0-degree Trial Abutment onto the emplaced implant, to provide a rough indication of the implant's insertion angle. The clinician then selects the Trial Abutment with the closest prosthetic angle to that established with the 0-degree Trial Abutment, and inserts the same into the implant, ensuring that the hex of the Trial Abutment engages with the internal hex of the implant and checking that the orientation of the Trial Abutment is optimised by indexing the same in the six available positions. The clinician may wish to try other Trial Abutments to determine if a better correction to the implant's insertion angle is possible with a differently-angled Trial Abutment.

The clinician should record the angle of the Trial Abutment which provides the optimal angular correction and order the prosthetic component (Screw-Retained Abutment or Ball Attachment) that corresponds to the angle of Trial Abutment.

7.3 Placing prosthetic components

For affixing prosthetic components for temporary or final restorations, the relevant OsteoCare abutment should be placed upon the implant in the planned orientation, ensuring that the abutment is seated with the hexagonal interfaces of the abutment and implant fully engaged. The clinician can then screw in the AFS initially to finger-tightness using a 1.5mm Hex Driver, and then with the Torque Wrench and Torque Wrench Connector (or Ratchet-Connected Ball Driver) to confirm tightening to 30 Ncm torque; or alternatively using a 1.5mm Handpiece Driver attached to a dental handpiece, provided always that the clinician is able to control the applied torque to 30 Ncm (ie, that the dental handpiece has adjustable torque control). Where torque

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

control is not available using a dental handpiece, the clinician must only use the Ratchet and Torque Wrench to perform insertion. Do not exceed 30 Ncm torque.

In particular, the Ratchet-Connected Ball Driver can account for an angulated screw-access channel in a prosthetic restoration, which may benefit the clinician in moving the screw access hole to a less visible position in the restoration.

OsteoCare abutments which can be directly screwed into the implant (eg, the One-Piece Ball Attachment) can be tightened directly using the relevant Driver and Ratchet (One-Piece Ball Attachments – 2.4mm Over-Hex Driver) to 30 Ncm checked using the Torque Wrench.

In all cases, the relevant component should be re-tightened and re-checked after 10 minutes to account for any settling. Please refer to the AFS Tightening Procedure in the Clinical Manual.

7.4 Cover Screws and Healing Collars

In two-stage surgical protocols, implant cover screws are inserted using a 1.5mm Hex Driver tightened using finger pressure (or, where adequate torque control is available such as is with some electrical dental handpieces, to between 5 and 10Ncm). Do not use the Ratchet or Torque Wrench – this can result in the insertion torque exceeding 10Ncm and damage to the bone-to-implant interface when removing the Cover Screw at second-stage surgery.

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

Again, do not use the Ratchet or Torque Wrench to affix a Cover Screw or Healing Collar into position to reduce the risk of exceeding 10Ncm insertion torque.

8. FOLLOW-UP CARE

Patients should be instructed in appropriate oral hygiene and care of the implants and restorations. Periodic follow-up appointments should be made to confirm and maintain adequate function of the restoration and health of the surrounding tissue.

9. DOCUMENTATION

OsteoCare products are identifiable by their catalogue and lot numbers.

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

10. CONTRAINDICATIONS

Clinicians should be aware of any patient allergies that may lead to difficulties and discomfort for the patient related to the use of OC Reusable Instruments, for example titanium or vanadium allergy or hypersensitivity for the Socket Formers, and nickel or chromium allergy or hypersensitivity where Ridge Expanders, a Site Marker, or the Pilot Socket Former are used.

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

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

Please refer to the Clinical Manual for other contraindications related to assessment of the health characteristics of the patient.

11. WARNINGS

	The clinician must take appropriate steps during treatment to protect patients from the risk of swallowing or aspiration of small items such as Drivers, Handpiece Drivers, Torque Wrench Connectors, or Trial Abutments.

11.1 General

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

A failure correctly to assess and plan surgical intervention, including for bone volume augmentation procedures using Ridge Expanders or Socket Formers, may lead to permanent damage to patient tissues including sensitive structures such as nerves and the maxillary sinus. It is the clinician's responsibility to ensure that all surgical procedures are planned and performed according to generally accepted best practice and in accordance with the training provided in advanced surgical courses. The clinician must not perform such procedures without appropriate experience and/or recent training in the advanced surgical techniques required.

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

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

11.2 Use requirements

All OC Reusable Instruments and Other RIs must be cleaned, disinfected, and sterilised **before each use** in accordance with the procedure set out in section 4 (*Cleaning and sterilisation*) above. A failure adequately to perform this procedure represents a significant risk to patients upon whom surgical procedures involving such reusable instruments are to be performed.

Drivers and connectors

Drivers and Handpiece Drivers should be checked on a regular basis to ensure the hexagon is not rounded, as this can cause the driver to not fully engage in the implant or prosthetic component and may cause a delay in the procedure.

When affixing Final Abutments or PEEK Temporary Abutments to an implant, exceeding the maximum torque of 30Ncm to an Abutment Fastening Screw could result in the thread of the AFS and/or the implant being damaged.

When inserting a Cover Screw or Healing Abutment, exceeding the maximum torque for these components of 5 to 10Ncm could result in their cold-welding to the relevant implant. When the clinician comes to remove a Cover Screw or Healing Collar which has cold-welded to the implant, attempting to remove the Cover Screw/Healing Collar could result in implant failure arising from damage to the connection between the implant and the peri-implant tissues.

Osteotomes

The Site Marker and Pilot Socket Former each have a sharp point. They therefore present a hazard to the clinician, to the patient, and to support staff in relation to puncture wounds (ie, sharps injuries), as well as transmission of blood borne infection via such wounds.

The clinician and staff must ensure that the Site Marker and Pilot Socket Former are: (1) used with the requisite level of care according to best clinical practice; and (2) cleaned with adequate attention paid to their sharp points.

11.3 Training

The information provided in these Instructions for Use and/or in the Clinical Manual is by itself not sufficient for a dental professional to use or place OsteoCare products if he or she has not undergone the necessary

specialised training. Clinicians must undergo specialised training in the placement of dental implants and associated surgical, planning, and restorative techniques. The use of Socket Formers and Ridge Expanders, in particular, involves advanced surgical techniques that a clinician should not undertake without some experience of hands-on training on a suitably accredited course. OsteoCare provides training and technical advice in the use of its system, including advanced courses providing training in advanced surgical techniques. Requests for such training/advice can be made using the contact details provided in Section 15 (*Manufacturer and EU authorised representative*) hereto.

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

12. UNDESIRABLE SIDE-EFFECTS

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

13. SERIOUS INCIDENT REPORTING

Patients and/or clinicians: in the event of a serious incident occurring which is caused by the device or a result of its use, please report the incident without delay to OsteoCare at info@osteocare.uk.com or by telephone at +44 (0)1753 770006, providing details of the incident. The same information must be provided to the national competent authority of the patient/clinician.

OsteoCare will provide a template report for completion by the clinician. If you are not certain whether the incident is serious, or that it has been caused or at least partially caused by the OsteoCare device, then please err on the side of caution and report the incident to OsteoCare.

14. DISPOSAL

Reusable instruments should be disposed of in accordance with local laws and regulations for the disposal of surgical equipment. This must include disposal into sharps boxes (where relevant) and segregation of such waste until final removal.

15. MANUFACTURER AND EU AUTHORISED REPRESENTATIVE

	Manufacturer: OsteoCare Implant System Limited 5-7 Colndale Road Poyle Industrial Estate Colnbrook Slough Berkshire SL3 0HQ United Kingdom	*Contact details:* Telephone: +44 (0)1753 770006 Fax: +44 (0)1753 770009 Sales: +44 (0)800 281 981 Email: Info@osteocare.uk.com
EC REP	*EU authorised representative:* Advena Ltd. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta	*Contact details:* Email: ec-rep@advena.mt

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