Burs instructions for use

These Instructions for Use (IFU) cover the following OsteoCare components:

Burs

- Universal Burs
- STS Burs
- Ultra Drills
- Ultra Stop Drills

Bur accessories

- Bur Extender
- Bur Cleaner
- Drill Stops
- Titanium Guide Tubes

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

The OsteoCare burs (Universal Burs, STS Burs, Ultra Drills, and Ultra Stop Drills) and related equipment set out above (Bur Extender, Bur Cleaner, Drill Stops, Titanium Guide Tubes) (together, the "bur accessories") are for use only with OsteoCare dental implants and/or other OsteoCare components for which they are designed (including the bur accessories) unless otherwise stated.

(1) 	Please refer to the packaging and label of your device to identify the details (range and size) of the medical device to be used. Also to be found on the packaging and label, are provided (each beside the relevant standard symbol reproduced here for convenience): (1) confirmation that the item is a medical device; (2) lot number; (3) date of manufacture; (4) catalogue reference of the device; (5) caution (in relation to the sharp edges/point of burs); (6) consult instructions for use; and (7) applicable only to the packaging for Titanium Guide Tubes, they are intended for single use only.
(2) 	
(3) 	
(4) 	
(5) 	
(6) 	
(7) 	
	**The OsteoCare burs and bur accessories 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 and instruments for the maintenance of hygiene standards during surgery, in accordance with the procedure described in section 5 (*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
506091295BursKT	Universal Burs	IN-UBR-[XXX]
	STS Burs (also: Universal Burs Stainless Steel)	IN-STS-[XXX]
	Ultra Drills	IN-PBR-[XXX]
	Ultra Stop Drills	IN-STB[Y]-[XXX]
Not applicable	Bur Extender	IN-BRE-001
	Bur Cleaner	IN-BRC-001
	Drill Stops	IN-DSC-[XXY]
506091295GuideTubesKX	Titanium Guide Tubes	CO-TGT-001

2. PRODUCT PACKAGING

OsteoCare burs are supplied as non-sterile as part of a kit (Surgical Kit or Universal Surgical Kit, or as a set of drills), or in a tamper-proof blister pack. If you receive an OsteoCare bur which appears damaged upon receipt from OsteoCare, please return the same to OsteoCare for replacement.

3. DESCRIPTION

3.1 Burs

An OsteoCare bur is a reusable instrument made of titanium alloy 6Al-4V ELI (Universal Burs) or stainless steel 17-4PH (STS Burs, Ultra Pilot/Profile/Stop Burs) which is used to prepare a cylindrical or conical osteotomy into which an OsteoCare dental implant is placed. It is to be affixed to any Type 1 motorised dental handpiece as a means of providing the angular momentum necessary for the sharp point/edges of the bur to cut into the bone.

There are depth markings on OsteoCare burs to allow the clinician to estimate the depth to which the bur has been inserted into the bone during drilling, and therefore the osteotomy depth. Universal Burs (titanium alloy) include an internal irrigation channel which allows cooled physiological saline to be pumped to the cutting face of the bur during drilling. All burs (including Universal Burs) should be used with external irrigation using physiologically cooled saline.

A Bur Extender can be used to increase the distance between the dental handpiece and the bur tip in circumstances where the dental handpiece would otherwise be obstructed by anatomical structures in the mouth. It replicates the shaft of a bur for fixation to the dental handpiece, and the aperture of the dental handpiece for fixation to the bur. The angular momentum imparted by the dental handpiece is thereby transferred by the Bur Extender from the dental handpiece to the bur.

3.2 Bur Cleaner

A Bur Cleaner is an accessory to Universal Burs for cleaning the internal irrigation channel which runs down the central axis of the bur. It comprises a finger grip at one end, and a narrow pin with a semi-circular cross-section tip with which to scoop out any surgical debris which has accumulated during the previous use.

3.3 Drill Stops

A Drill Stop provides a means by which the depth of an osteotomy can be controlled during drilling. It is made of an engineering plastic – polyether ether ketone (PEEK) – and comprises a central hole through which the shaft of a bur is placed before the bur is inserted into the dental handpiece.

With the Drill Stop in position, the shoulder of the bur sits against the internal face of the Drill Stop, while the

side of the Drill Stop extends a set distance (depending upon the selected Drill Stop) towards the cutting tip of the bur. As the bur is inserted into the bone, it will come up against the tip-ward extension of the Drill Stop, and prevent further insertion of the bur.

3.4 Titanium Guide Tubes

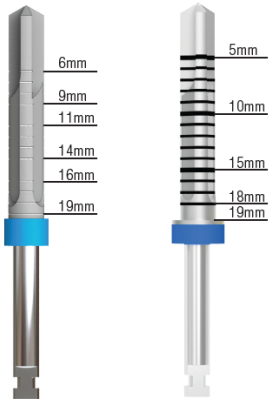
Titanium Guide Tubes are single-use components which are cemented into custom-manufactured surgical guides for guided surgery.

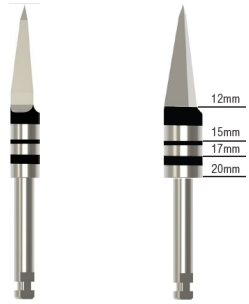
4. INTENDED USE

4.1 Burs

OsteoCare burs and bur accessories are for use only 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*).

<table>
<tr>
<td> 

Ultra Pilot (Short and Long) Burs, showing depth markings</td>
<td rowspan="2">Ultra Pilot Drills, Universal Burs, and STS Burs are intended for osteotomy preparation for implant placement in the upper or lower jaw.
They are for indicated for conventional sequential drilling protocols in D1 to D4 bone according to the relevant suggested drilling guidelines included in the Clinical Manual. In all sequential drilling protocols, whether in healed bony sites or extraction sockets, the Ultra Pilot is ideally suited to providing the pilot osteotomy for subsequent enlargement (according to the relevant drilling protocol) by Universal or STS Burs.
Ultra Pilot Drills are also indicated for single-drill procedures for the placement of Mini/Midi Post- and Ball-Type implants in healed bony sites in D1 to D3 bone, or immediately post-extraction in D2 and D3 bone.
For Ultra Pilot Long burs, Universal, and STS Burs, depth markings provide a visual guide to the clinician in determining the depth to which the bur has been inserted into the bone. The depth markings are measured from the apex of the cutting tip, which has a 120-degree point angle.</td>
</tr>
<tr>
<td> 

Universal Bur and STS Bur, showing depth markings</td>
</tr>
<tr>
<td> 

Ultra Profile Burs, showing 3.25mm and 4.0mm diameter versions.</td>
<td>Ultra Profile Drills are used for osteotomy preparation for placement in the upper or lower jaw in D2 to D4 bone. They may be used for placement of the Maxi Z (One-Piece and Two-Piece) and Maxi Z Plus, depending upon the relevant platform diameter. Their use is more limited for Maxi Z Flat-End implants, and they are not indicated for use for cylindrical implants (ie, Advanced, Classic Advanced, or Classic 2 Advanced implants.
They are intended for single drill procedures, rather than sequential drilling protocols, in accordance with the relevant suggested drilling guidelines included in the Clinical Manual.</td>
</tr>
</table>

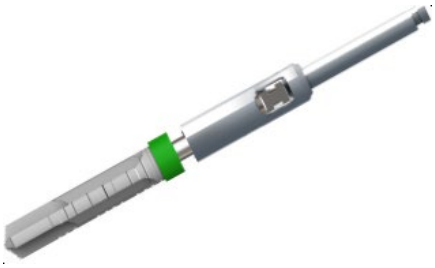
 Ultra Stop Drills	Ultra Stop Drills are for osteotomy preparation for placement in the upper or lower jaw, and are particularly suited to D1 and D2 bone. They are intended to be used for Maxi Z Flat-End Implants, with the specific size of Ultra Stop Bur to be used with the corresponding size of the Maxi Z Flat-End Implant. They should ordinarily be used following pilot hole creation at the site of the implant bed using the Ultra Stop Pilot Drill.

Guidelines for drilling protocols for all OsteoCare implants are included in the Clinical Manual. These are recommendations which have been established through extensive use of OsteoCare burs, and are thus intended to reflect best practice.

All osteotomy preparation should be performed at 1,200 to 2,000 RPM and accompanied by copious irrigation, including both internal *and* external irrigation when using Universal Burs.

OsteoCare recommends replacement of Burs after 25 uses. A Bur must be replaced sooner if it shows signs of excessive wear, where drilling efficacy is noticeably reduced, or where the osteotomy shows excessive eccentricity due to the Bur no longer cutting strictly circularly.

4.2 Bur accessories

	A Bur Extender may be used with any OsteoCare bur to allow drilling in positions where adjacent teeth or other anatomical structures present an obstacle to the dental handpiece during normal use of the bur. The Bur Extender works by extending the distance between the cutting tip of the bur and the head of the dental handpiece.
	The Bur Cleaner is for the removal of surgical debris from the lumen following surgery by full insertion into the lumen, rotation through a full revolution, and removal.
	Drill stops are designed to precisely control osteotomy size by reducing the depth to which the bur can be inserted into the bone. Drill Stops are available as part of a set, with incremental (1.0mm) drilling depth reduction between 5.0 and 16.0mm. Thus a Drill Stop A (IN-DSC-05A) will reduce the maximum drilling depth of a bur by 5.0mm; Drill Stop B (IN-DSC-06A) by 6.0mm, etc. The front edge of the Drill Stop prevents further insertion, so it is important for the clinician to ensure that he/she/they is aware of the: (1) the required osteotomy depth; and (2) any allowance necessary for gingival thickness (if flapless surgery)
	TGTs are fixed into a surgical guide to orient and position the bur during osteotomy preparation, reducing the risk of damage to sensitive anatomical structures and of poor positioning of the implant. Surgical guides may be manufactured using a diagnostic wax-up using data based on radiographs and intraoral examination, or from cone beam computerised tomography (CBCT) data using appropriate digital planning software.

5. CLEANING AND STERILISATION

OsteoCare burs are delivered decontaminated but **non-sterile**. **All surgical instruments including OsteoCare burs must be cleaned, disinfected, and sterilised before surgery to minimise the risk of bacterial and/or viral infection from contaminated instruments.**

Burs and Burs Accessories 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 Burs and Bur Accessories must be removed from any kit box/tray** (eg, the Universal Surgical Kit box/tray) **and cleaned individually**, and the instrument tray (of the Universal Surgical Kit) 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 Burs and Bur Accessories (excluding Guide Tubes, which are single-use components) 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.

Surgical guides (into which one or more Guide Tubes have been inserted) must be cleaned to remove any debris that arises during preparation, and must also be sterilised (if not already provided to the clinician in a cleaned and sterile condition). The user should refer to the surgical guide manufacturer for cleaning and sterilisation requirements. In the absence of such guidance, the cleaning steps set out below for reprocessing of Burs and Bur accessories may be adopted.

5.1 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 gross soiling as possible from instruments (including Burs and Bur Accessories) 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.

5.2 Preparation before cleaning

Disassembly	• Remove the item from direct packaging. Where part of a kit, remove the Bur/Bur Accessory 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 Bur/Bur Accessory 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, or cavities of all visible soil using cold tap water for at least 10 seconds.

5.3 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	Individual components or small instruments • 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. Kits • 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 into the automated washer-disinfector used during processing)	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. • 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.

5.4 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.

5.5 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.

5.6 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.

5.7 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.

5.8 Manufacturer contact

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

6. INDICATIONS FOR USE

OsteoCare burs are indicated for performing osteotomies for implant bed preparation for the placement only of OsteoCare implants in adults. They should be used in accordance with the implant-specific drilling protocols provided in the Clinical Manual.

Drill Stops are indicated for use only with STS burs to reduce the depth to which a bur can be inserted into the bone during osteotomy preparation.

7. SURGICAL PROCEDURES

For a detailed explanation of procedures for the use of OsteoCare burs and/or Drill Stops, including drilling guidelines, please refer to the Clinical Manual.

7.1 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.

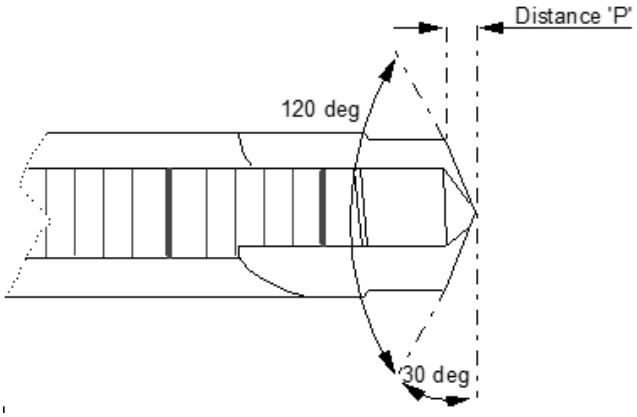
A number of factors must be taken into consideration during the planning process, including: the patient's needs and physical characteristics, the biomechanics of the proposed restoration, the neighbouring and opposing teeth, the occlusal and articulation conditions, phonetic aspects, aesthetics (dental,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

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

For STS Burs and Universal Burs, the clinician may also need to account for the reduction in parallel section of the implant bed which arises because of the 120-degree point angle. This reduction is calculated as the radius of the Bur divided by tan 30°, which is more simply diameter * 0.29). The table below sets out the simple corrections required:

Bur diameter/mm	Colour code	Parallel reduction (P)/mm
2.2	White	0.64
2.5	Red	0.73
2.75	Yellow	0.80
3.25	Light blue	0.94
4.0	Green	1.16
4.4*	Grey	1.16 and 0.12
4.8*	Dark blue	1.16 and 0.23

Diagram:



* - the 4.4 and 4.4mm diameter Burs are stepped, with a lead-in diameter of 4.0mm. Since OsteoCare does not market cylindrical 5.5mm diameter implants (the Maxi Z ranges are root form), it is very unlikely that the clinician will need to take this into account. The distances are nevertheless provided for completeness.

7.2 Bur selection

As part of the planning process, the clinician must ensure that he/she/they is aware of the Burs required during surgery, and that these have been identified correctly in advance. For sequential drilling protocols in which STS or Universal Burs are to be used, each Bur is colour-coded to provide confirmation to the clinician during use that the correct Bur has been selected. Clinical staff providing support during surgery must be aware of the protocol to be employed during the surgery so that mistakes can be avoided.

Clinicians with colour vision deficiency should take extra care in ensuring in advance of surgery that the correct Burs have been selected where sequential drilling protocols are to be used.

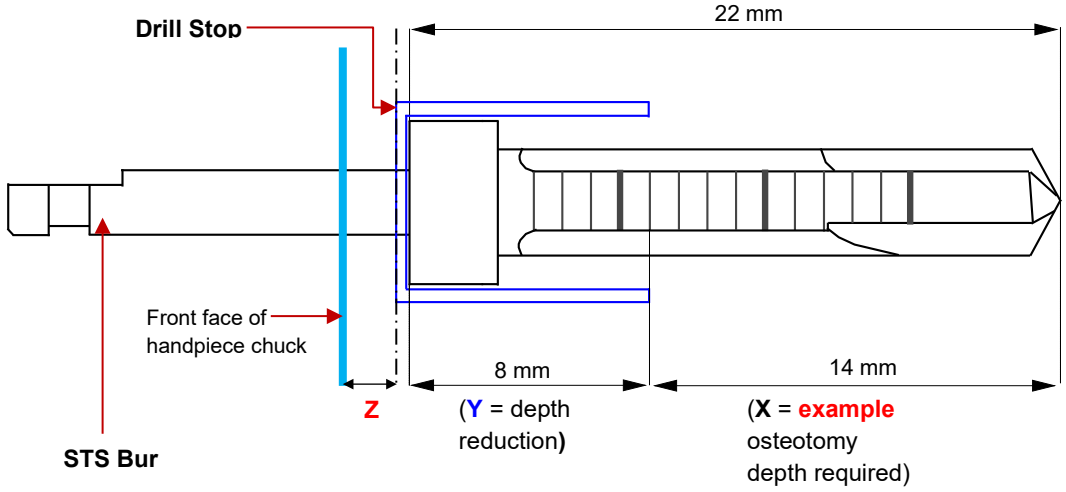
7.3 Drill Stop selection

The *drilling guidelines* remain applicable and should be applied in accordance with the instructions in the Clinical Manual. Please note that a minimum gap of at 7.0mm must be available between teeth to allow use of a Drill Stop at the edentulous site, and at positions with such limited available space, the implant bed may only be positioned at the mid-point between teeth

Each drill stop is engraved with a different letter which uniquely identifies it according to the reduction in the drilling depth that it provides. The following steps apply for selection according to the osteotomy depth required (please refer to the accompanying diagram immediately below):

- determine the depth ("**X**") of the osteotomy required according to the implant to be placed and the drilling guidelines;
- The Drill Stop drilling depth reduction ("**Y**") is determined by reference to the box and table below. Example:

Side view of bur with Drill Stop (cross-sectional view) in position:



Drill stop selection example

- the relevant length of the drill is 22mm (see diagram);
- X = 22 – Y;
- in the diagram, the osteotomy depth required has been determined in advance as 14mm. The depth reduction required is therefore 22 – 14 = 8mm (ie, Y = 8mm).
- **The required Drill Stop must therefore provide a drilling depth reduction of 8mm, which is Drill Stop "D"** (ie, IN-DSC-0D8).

Accounting for the handpiece chuck position

OsteoCare has tested drill stops with a number of different dental handpieces. With the drill stop in position, and the drill engaged in the handpiece chuck, the distance between the back of the drill stop and the front face of the handpiece chuck (in the drawing, denoted "Z") is no more than 0.5mm in testing.

Nevertheless, OsteoCare has not exhaustively verified the connection between dental handpieces and STS Burs, and there may be instances in which the distance Z exceeds 0.5mm. Where this is the case, the value of Z must be accounted for, since during drilling the drill stop will be pushed back by this distance and thereby increase the drilling depth by this same distance.

Therefore, when checking the selection of the drill stop using the ruler provided on the drill stop container, please ensure that with the STS Bur inserted into the ruler, the drill stop is pushed with a moderate force against the edge of the drill stop container so that the rear face of the drill stop is against the front face of the handpiece chuck.

Drill stop selection guidelines

These are indicative only, and do not account for Z being greater than 0.5mm:

Drill stop label	Depth reduction (Y) (mm)	Required osteotomy depth (X) mm
A	5	17
B	6	16
C	7	15

D	**8**	14
E	9	13
F	10	12
G	11	11
H	12	10
J	13	9
K	14	8
L	15	7
M	16	6

You must verify that the selected Drill Stop provides the correct reduction ensuring that you consider any allowance for gingival thickness where flapless surgery is to be performed, since osteotomy depth will be reduced by the thickness of the gingiva at the implant bed site.

7.4 Surgical guides

Context of use

The Titanium Guide Tubes are for use in partial guided surgery, to allow the clinician to make pilot holes to a depth and orientation for sequential drilling of an implant bed. The Titanium Guide Tube can only be used in a surgical guide for placement of the initial pilot hole of the implant bed because the inner diameter **is suitable only for a 2.2mm Universal Bur or STS Bur**. Once the pilot hole has been placed, therefore, sequential drilling takes place without a surgical guide.

Procedure

The clinician takes a cast impression or a digital impression of the patient's jaw. The clinician or laboratory then determines the orientation and depth required for the pilot hole for the implant bed.

The clinician or laboratory makes the surgical guide, either conventionally (using the cast model of the patient's jaw) or via 3D printing.

The clinician determines the insertion depth required for the implant bed (ensuring always that he/she/they accounts for any sensitive anatomical structures), and cuts (or the dental technician cuts) the Guide Tube using a disc cutter[1] so that: (1) if necessary, the Guide Tube prevents the insertion of the pilot drill beyond a safe depth in the patient's jaw; and (2) when cemented into the surgical guide, the apical end of the Guide Tube is at a level at least 2mm above the lower surface of the surgical guide, to allow the clinician to see the bur forming the pilot hole, and to allow adequate irrigation.

7.5 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. Relevant instructions for use should be followed to ensure that components including OsteoCare burs and implants are not damaged during surgery and that surgical trauma to patient tissues is minimised.

OsteoCare-recommended drilling guidelines are included in the Clinical Manual, and which set out suggested drilling sequences relevant to specific OsteoCare implant ranges, implant size, bone types, and site type (ie, in healed sites or immediately post-extraction).

Drill rotation rate should remain high during drilling but should not exceed 2,000 RPM. Drilling must be performed under continuous, copious, cooled irrigation using physiological saline and, for Universal Burs, should be both internal *and* external where possible. The clinician should monitor the cutting efficacy of OsteoCare burs including during surgery to minimise the risk of trauma to peri-implant tissues. Where a surgical template is used to guide the direction and depth of drilling during surgery, the clinician should use a *pecking* technique in which the cutting tip is regularly lifted clear of the surgical template. This will allow (1) the escape of surgical debris caught in the flutes of the relevant bur; and (2) irrigation to cool both the cutting tip and the newly-cut bone at the apex of the implant bed.

---

[1] The retained part of the Guide Tube for inclusion in the surgical guide includes the lead-in cone.

7.6 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.

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.

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

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 OsteoCare burs and bur accessories, for example titanium, vanadium, stainless steel, and/or nickel allergy or hypersensitivity.

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

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

11. WARNINGS

	**Titanium Guide Tubes are intended for single use only and are labelled as such. Re-use of products labelled as single use only may result in product contamination, patient infection and/or failure of the device to perform as intended.**
	**Some OsteoCare components and instruments (including Burs) 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[2], including checking that the Bur is properly mounted on the dental handpiece. Activating the handpiece before use in the patient's mouth will confirm whether the Bur is properly installed.**

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

11.1 General

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

A failure correctly to assess and plan surgical intervention, including osteotomy site preparation using OsteoCare burs, may result in permanent damage to patient tissues including sensitive structures such as nerves and the membranes of the sinus. It is the clinician's responsibility to ensure that all surgical procedures are performed according to generally accepted best practice and in accordance with instructions for use and the Clinical Manual. It is also the clinician's responsibility to ensure that he or she is familiar with the latest developments in clinical practice (via accredited continued professional development such as training provided by OsteoCare, and via regular reviews of scientific literature) and that he or she has reviewed the latest version of the Clinical Manual, which is available at https://osteocare.uk.com/eifu/ and which is regularly updated.

Users of OsteoCare products must decide whether the application of the product is or is not suitable for the specific conditions. In case of doubt, the user should contact OsteoCare using the contact details provided herewith.

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 OsteoCare burs must be cleaned, disinfected, and sterilised **before each use** in accordance with the procedure set out in section 5 (*Cleaning and sterilisation*) above. A failure adequately to perform this procedure represents a significant risk of serious viral and/or bacterial infection to patients upon whom surgical procedures involving a bur are to be performed.

The clinician must examine and monitor a bur for signs of wear or reduced cutting efficacy. A failure to do so may result in damage to peri-implant bone, including in particular overheating leading to thermal necrosis of the bone and a failure of the implant to osseointegrate. **OsteoCare recommends replacement of Burs after a maximum of 25 uses: the clinician should take particular care if intending to continue using a Bur beyond the recommended maximum**.

If intending to use the Bur Extender, the clinician must perform a visual inspection to ensure that there is no surgical or other debris which would adversely affect the connection with a bur, and should perform a test with a bur (ensuring sterility is maintained if the instruments have already been cleaned and sterilised) to check that the connection is performing as intended.

OsteoCare burs should only be used axially, so that no lateral pressure is placed upon the bur when inserted whether fully or partially. Where used as part of a sequential drilling protocol, insertion of each bur must follow the same axis as the previous bur.

OsteoCare burs are tools for cutting into bone, and they all have sharp edges to facilitate this purpose; Ultra Pilot and Ultra Profile Burs additionally have a sharp cutting tip. They therefore present a hazard to the clinician, to the patient, and to support staff in relation to puncture wounds and cuts (ie, sharps injuries), as well as transmission of blood borne infection via such wounds and/or cuts.

The clinician and staff must ensure that burs are: (1) used with the requisite level of care according to best clinical practice; and (2) cleaned with adequate attention paid to points/edges.

The Bur Cleaner also presents a puncture wound risk if not used with adequate care and attention during cleaning of Universal Burs.

Use of a Guide Tube with a drill for which the diameter is greater than 2.2mm will result in a failure to produce a pilot hole using the surgical guide, and generate wear particles (most likely of titanium dioxide and/or bulk titanium) in the patient's mouth. Use of a Guide Tube with under-sized drills may result in angular and positional discrepancies for the pilot hole which can increase the risk of damage to sensitive anatomy in the patient's mouth as well as planning failures.

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. OsteoCare strongly recommends that clinicians undergo specialised training in the placement of dental implants and associated surgical, planning, and restorative techniques. OsteoCare provides training and technical advice in the use of its system. Requests for such training/advice can be made using the contact details provided in Section 15 (*Manufacturer and EU authorised representative*) hereto.

All clinical 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. In case of doubt as to whether an incident is serious or not, please err on the side of caution and report the incident.

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

OsteoCare burs should be disposed of in accordance with local laws and regulations for the disposal of surgical equipment. This must include disposal into sharps boxes 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

CE 0413

MADE IN BRITAIN