SOUTHERNIMPLANTS®
Innovative Treatment Solutions

English	**INSTRUCTIONS FOR USE: Southern Implants® Counter bores and Counter sinks**
Español	**INSTRUCCIONES DE USO: Southern Implants® Counter bores and Counter sinks**
Italiano	**ISTRUZIONI PER L'USO: Southern Implants® Counter bores and Counter sinks**
Français	**MODE D'EMPLOI : Southern Implants® Counter bores and Counter sinks**
Deutsch	**GEBRAUCHSANWEISUNG: Southern Implants® Counter bores and Counter sinks**
Português	**INSTRUÇÕES DE UTILIZAÇÃO: Southern Implants® Counter bores and Counter sinks**

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Intended Use
Southern Implants® Counterbores and countersinks are intended to be used to prepare the osteotomy for implant placement. These are medical devices, intended for single use on a single patient.

Intended user
Maxillo-facial Surgeons, General Dentists, Orthodontists, Periodontist, Prosthodontists and other appropriately trained and experienced implant users.

Intended environment
The devices are intended to be used in a clinical environment such as an operating theater or a dentist consultation room.

Intended patient population
Patients that have lost one tooth or multiple teeth and are having dental implants inserted.

Description
Southern Implants counterbores and countersinks are described in Table 1 and Table 2, respectively. These devises attach to a handpiece of an implant motor unit, and has a latch dimension compatible to ISO 1797. This is in order to connect the device to the handpiece of an implant motor unit. Counter bores have a laser marked line in the cutting part to indicate depth of drilling, and a laser marking on the shaft to indicate the increase in diameter of the osteotomy. Counter sinks have laser marked lines in the cutting part to indicate depth of counter sinking.

Table 1

COUNTER BORES

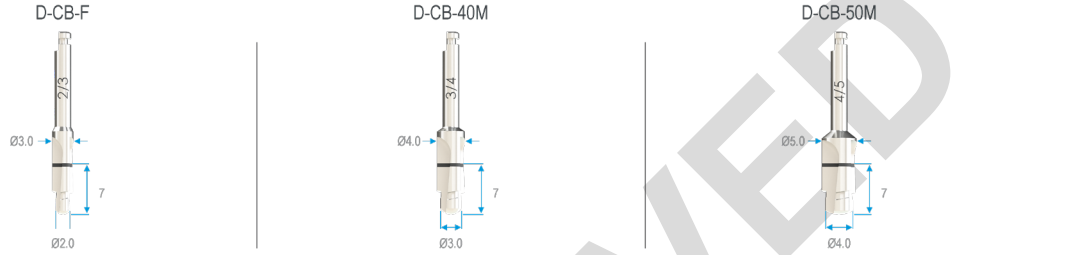
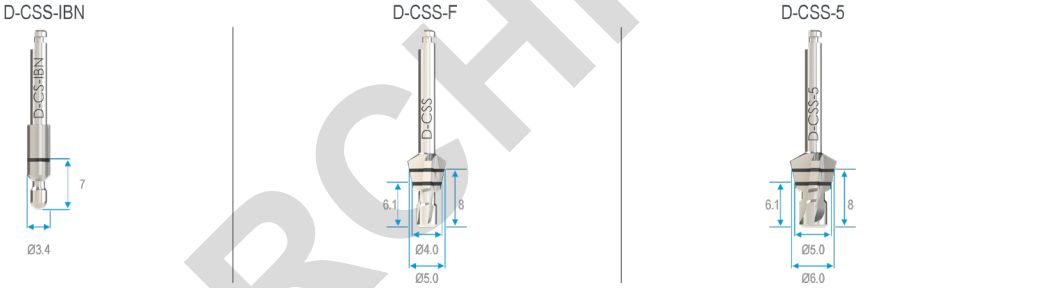


Table 2

COUNTER SINKS



Indications for use
A countersink is a surgical instrument designed to enlarge the diameter of the proximal portion of a hole drilled in bone in order to resess the top of the implant or abutment within the bone. (enable to lie flush with or below the crestal bone surface)

A counterbore is a surgical instrument used to create a cylindrical flat-bottomed hole that enlarges another coaxial hole. Counterbores are used to essentially create a cylindrical cavity at the head of an already drilled hole, in order to guide a larger drill.

Contraindications
Do not use in patients:
- who are medically unfit for dental implant procedures.
- where adequate numbers of implants could not be placed to achieve full functional support of the prosthesis.
- who are allergic or have hypersensitivity to pure titanium or Titanium alloy (Ti-6Al-4V), gold, palladium, platinum, iridium, Stainless steel and Radel.
- who are under the age of 18, have poor bone quality, blood disorders, infected implant site, vascular impairment, uncontrolled diabetes, drug or alcohol abuse, chronic high dose steroid therapy, anti-coagulant therapy, metabolic bone disease, radiotherapy treatment.

Warnings
THESE INSTRUCTIONS ARE NOT INTENDED AS A SUBSTITUTE FOR ADEQUATE TRAINING.
- For the safe and effective use of dental implants, it is suggested that specialised training be undertaken, including hands-on training to learn proper technique, biomechanical requirements and radiographic evaluations.
- Responsibility for proper patient selection, adequate training, experience in the placement of implants, and providing appropriate informed consent rests with the practitioner. Improper technique can result in implant failure, damage to nerves/vessels and/or loss of supporting bone.
- The use of non-sterile items can lead to secondary infections of the tissue or transfer infectious diseases.

Cautions
New and experienced Implant users should do training before using a new system or attempt to do a new treatment method. Take special care when treating patients who have local or systemic factors that could affect the healing of the bone and soft tissue i.e. poor oral hygiene, uncontrolled diabetes, are on steroid therapy, smokers, infection in the nearby bone and

patients who had oro-facial radiotherapy.
Thorough screening of prospective implant candidates must be performed including:

- A comprehensive medical and dental history.
- Visual and radiological inspection to determine adequate bone dimensions, anatomical landmarks, occlusal conditions and periodontal health.
- Bruxism and unfavourable jaw relations must be taken into account.
- Proper pre-operative planning with a good team approach between well trained surgeons, restorative dentists and lab technicians is essential for successful implant treatment.
- Minimizing the trauma to the host tissue increases the potential for successful osseointegration.
- Electro-surgery should not be attempted around metal implants, as they are conductive.

During surgery

Care must be taken that parts are not swallowed during any of the procedures, a rubber-dam application is recommended when appropriate.

Post-surgery

Regular patient follow-up, and proper oral hygiene must be achieved to ensure favourable long-term results.

Storage, cleaning & sterilisation

These devices are supplied sterile (sterilised by gamma irradiation). Sterility is assured unless the, container or seal is damaged or opened. If packaging is damaged do not use the product and contact your Southern representative/ or return to Southern Implants. The devises must be stored in a dry place at room temperature and not exposed to direct sunlight. Incorrect storage may uence device characteristics.

Single use devices:
Do not reuse devices indicated for single use. (Use the device prior to the expiration date).
Do not reuse implants, single use drills, cover screws, temporary abutments and abutments. Reusing these components may result in:

- Damage on the surface or critical dimensions, which may result in performance and compatibility degradation.
- Adds the risk of cross-patient infection and contamination if single-use items are reused.

Southern Implants does not accept any responsibility for complications associated with reused components.

Sterilisation

Southern Implants recommends the following procedure to sterilise the instruments prior to use when packed in a tray.

Methods to sterilise these devises:
1. Pre-vacuum Sterilisation method: Steam sterilise the instruments at 132°C (270°F) at 180-220kPa for 4 minutes. Dry for at least 20 minutes in the chamber. Only an approved wrap or pouch for steam sterilisation must be used.
2. Pre-vacuum sterilisation method: Wrapped, steam sterilise at 135°C (275°F) for 3 minutes. Dry for 20 minutes in the chamber. Use a wrap or pouch that is cleared for the indicated steam sterilisation cycle.

Note: Users in the USA must ensure that the steriliser, wrap or pouch, and all steriliser accessories are cleared by the FDA, for the intended sterilisation cycle.

Clinical procedures

A proper clinical and radiological evaluation must be done to determine the bone dimensions and bone quality.

Before Surgery

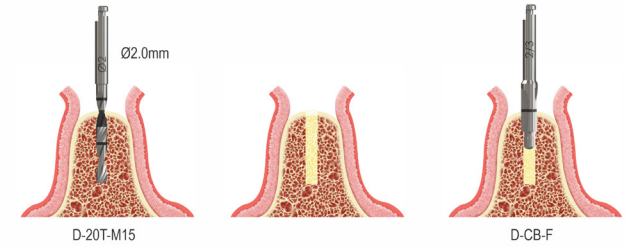
All components, instruments and tooling used during the clinical or laboratory procedure must be maintained in good condition and care must be taken that instrumentation does not damage implants or other components.

Surgical procedure

Counterbores

Southern Implants provides the user with drill options for placement of tapered and parrallel walled implants, depending on the bone quality. All drilling is performed at speed of 1000-1500rpm, with constant irrigation with sterile saline.

Fig 1



- After initiating the Osteotomy and subsequent use of the Ø2mm twist drill, the counterbore (D-CB-F) is used to increase the crestal diameter of the osteotomy to 3mm, to accept and guide the Ø3mm twist drill. D-CB-F apical tip is Ø2mm, drill up to the lasermarking line on the counter bore – the crestal part will then be drilled to Ø3mm and 7mm deep.

Similarly the counterbore D-CB-40M will increase the crestal diameter from Ø3mm to Ø4mm to accept and guide the Ø4mm twist drill.

When placing wider diameter Implants it will be necessary to use the D-CB-50M to increase the crestal diameter from Ø4mm to Ø5mm to accept and guide the Ø5mm twist drill.

Countersink

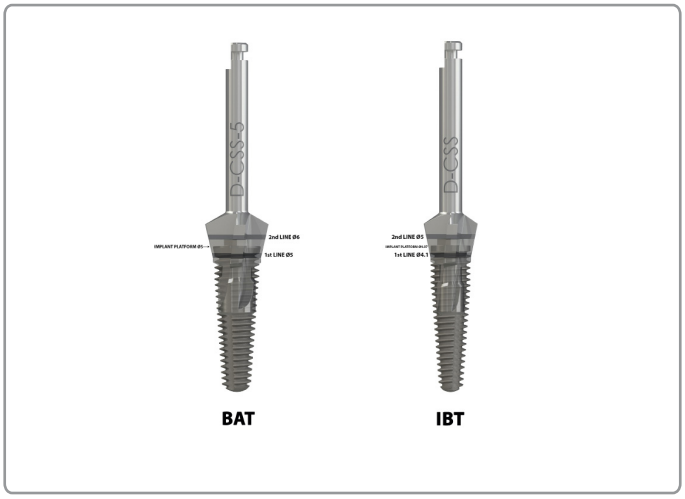
Southern Implants provides the user with counter sinks for when the implant is placed sub-crestal, or to seat the implant platform at bone level.

All drilling is performed at speed of 1000-1500rpm, with constant irrigation with sterile saline.

Countersink is used when the protocol require the implant to be placed subcrestal or to seat the top of the implant at bone level.

The lines on the countersink indicate the diameter and will determine the drilling depth according to surgical planning (Fig 2). Make sure to use a drill compatible with the indicated drilling sequence according to the prosthetic interface and dimensions of the planned implant.

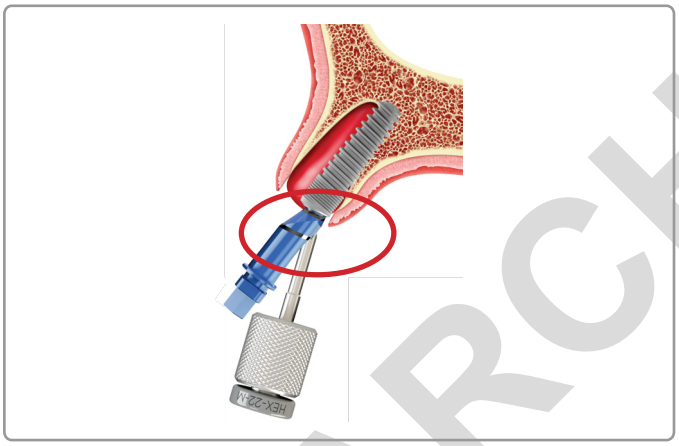
Fig 2



Co-Axis

When placing a Co-axis implant, depending on the gap between the planned implant and the palatal bone plate, deeper countersinking may be appropriate to avoid interference of bone when seating the implant and removal of the Fixture mount (Fig 3).

Fig 3



Clinical bene ts

Patients can expect to have their missing teeth replaced and/ or crowns restored. Screwdrivers are used in dental procedures or in dental implant crowns & bridges. It is the responsibility of the practitioner to decide when the implant can be restored. Good primary stability will govern if immediate loading can be done.

Implant care and maintenance

Potential implant patients should establish an adequate oral hygiene regime prior to Implant therapy. Proper post-operative, oral hygiene and implant maintenance instructions must be discussed with the patient, as this will determine the longevity and health of the Implants. The patient should maintain regular prophylaxis and evaluation appointments.

Material

Counter bore: Stainless steel
Counter sink: Stainless steel

Potential Side and Temporary symptoms: Pain, swelling,

More persistent symptoms: The risks and complications with implants include, but are not limited to: (1) allergic reaction(s) to implant and/or abutment material; (2) breakage of the implant and/ or abutment; (3) loosening of the abutment screw and/or retaining screw; (4) infection requiring revision of the dental implant; (5) nerve damage that could cause permanent weakness, numbness, or pain; (6) histologic responses possibly involving macrophages and/or s; (7) formation of fat emboli; (8) loosening of the implant requiring revision surgery; (9) perforation of the maxillary sinus; (10) perforation of the labial and lingual plates; and (11) bone loss possibly resulting in revision or removal.

Breakage

Implant and abutment fractures can occur when applied loads exceed the normal functional torque strength of the material. Potential overloading conditions may result from; ncies in implant numbers, lengths and/or diameters to adequately support a restoration, excessive cantilever length, incomplete abutment seating, abutment angles greater than 30 degrees, occlusal interferences causing excessive lateral forces, patient parafunction (e.g., bruxing, clenching), loss or changes in dentition or functionality, inadequate prosthesis , and physical trauma. Additional treatment may be necessary when any of the above conditions are present to reduce the possibility of hardware complications or failure.

Changes in performance

It is the responsibility of the clinician to instruct the patient on all appropriate contraindications, side and precautions as well as the need to seek the services of a trained dental professional if there are any changes in the performance of the implant (e.g., looseness of the prosthesis, infection or exudate around the implant, pain, or any other unusual symptoms that the patient has not been told to expect).

Disposal

Disposal of the device and its packaging; Follow local regulations and environmental requirements, taking di erent contamination levels into account. When disposing of spent items, take care of sharp drills and instruments. PPE must be used at all times.

Disclaimer of liability

This product is part of the Southern Implants product range and should only be used with the associated original products and according to the recommendations as in the individual product catalogues. The user of this product has to study the development of the Southern Implants product range and take full responsibility for the correct indications and use of this product. Southern Implants does not assume liability for damage due to incorrect use. Please note that some Southern Implants products may not be cleared or released for sale in all markets.

Notice regarding serious incidents

Any serious incident that has occurred in relation with the device must be reported to the manufacturer of the device and the competent authority in the member state in which the user and / or patient is established. The contact information for the manufacturer of this device to report a serious incident is as follows: sicomplaints@southernimplants.com

Basic UDI

Product	Basic-UDI Number
Basic-UDI for Drills and Handpiece Devices	600954403875

Related literature & catalogues

CAT-2004 - Tri-Nex Implants Product Catalogue
CAT-2005 - IT Implants Product Catalogue
CAT-2010 - Osseointegrated Fixtures Catalogue
CAT-2020 - External Hex Implants Product Catalogue
CAT-2042 - Deep Conical Implants Product Catalogue
CAT-2043 - Internal Hex Implants Product Catalogue
CAT-2060 - PROVATA® Implants Product Catalogue
CAT-2069 - INVERTA® Implants Product Catalogue
CAT-2070 - Zygomatic Implants Product Catalogue

Symbols and Warnings

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CE 2797

Sterilization using Irradiation

Non-sterile


Caution


Consult instruction for use


Use by date (mm-yy)

Do not reuse

Do not re-sterilize

Batch code


Do not use if package is damaged

Medical Device

* Prescription device: Rx only. Caution: Federal Law restricts this device to sale by or on the order of a licenced physician or dentist.

Canada licence exemption: Please note that not all products may have been licensed in accordance with Canadian law.