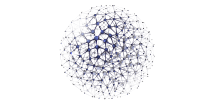
Surgical manual

CSR

sweden & martina

CSR



Clinical indications for resorting to implantoprosthetic therapies

When assessing the patient, in addition to his/her eligibility with regards to implant-prosthetic rehabilitation, it is usually necessary to consider the contraindications that apply to oral surgery procedures in general. These include:

- clotting disorders, anticoagulant therapy;
- healing or bone regeneration disorders;
- decompensated diabetes mellitus;
- metabolic or systemic diseases that compromise tissue regeneration with a particular influence on healing and bone regeneration;
- alcohol abuse, smoking and use of drugs;
- immunosuppressive therapy, such as: chemotherapy and radiotherapy;
- infections and inflammations, such as periodontitis and gingivitis;
- poor oral hygiene;
- inadequate motivation;
- occlusion and/or articulation disorders as well as inadequate interocclusal space;
- inadequate alveolar process.

It is contraindicated to fit implants and implant restorations in patients with poor general or oral health, those who are unable to monitor their general conditions properly or those who have had organ transplants. Psychologically unstable patients, alcohol or drug abusers, and poorly motivated or uncooperative patients should also be considered unsuitable for this kind of treatment. Patients with poor periodontal health should first be treated and allowed to recover. In the presence of a lack of bone substance or poor quality of the receiving bone, such as to compromise the stability of the implant, suitable guided tissue regeneration must be performed prior to implant treatment.

Contraindications also include: bruxism, allergy to titanium (extremely rare), acute or chronic infectious diseases, sub-acute chronic maxillary osteitis, systemic diseases, endocrine disorders, diseases resulting in microvascular disorders, pregnancy, breastfeeding, previous exposure to radiation, haemophilia, neutropenia, steroid use, diabetes mellitus, kidney failure and fibrous dysplasia. The normal contraindications common to all oral surgery must also be observed. Surgery is not recommended for patients on anti-coagulant, anticonvulsant and immunosuppressant therapies, with active inflammatory-infective processes of the oral cavity, and patients with BUN and creatinine values outside the norm. Patients with cardiovascular disease, hypertension, thyroid or parathyroid diseases, malignant tumours found in the 5 years preceding the operation, or nodular swellings must also be rejected.

Chemotherapies reduce or eliminate the ability of osseointegration, therefore patients undergoing these treatments must be carefully screened before being rehabilitated with oral implantoprostheses. Numerous cases of bisphosphonate-associated periimplant osteonecrosis of the mandible have been reported in the literature.
This problem particularly applies to patients treated intravenously.
As a post-operative precaution, the patient must avoid any kind of strenuous physical activity.

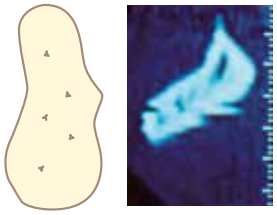
Side and secondary effects

Situations that may occur after surgical procedures include temporary local swelling, edema, hematoma, temporary sensitivity alterations, temporary masticatory limitations, post-surgical micro-hemorrhages in the following 12-24 hours. The patient may also experience pain, speech problems, gingivitis, loss of bone crest, permanent paresthesia, dysesthesia, local or systemic infections, exfoliation, hyperplasia, and oronasal and oroantral fistulas, perforation of the labial or lingual plate, perforation of the Schneidarian membrane, bone fractures, implant fractures, fractures of the over-structures, aesthetic problems, unnoticed perforation of the nasal sinus, nerve injuries, impairment of natural dentition. The following pathophysiological problems can increase the risks: cardiovascular failure, coronary disease, arrhythmia, pulmonary or chronic respiratory disease, gastrointestinal disease, hepatitis, inflammatory bowel disease, chronic kidney failure and disorders of the urinary system, endocrine disorders, diabetes, thyroid diseases, hematologic disorders, anaemia, leukaemia, coagulation problems, osteoporosis or musculoskeletal arthritis, stroke, neurological disorders, mental retardation, paralysis.

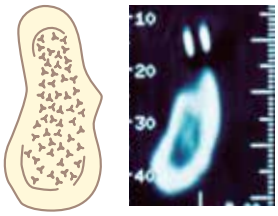
Before proceeding, it is important to perform a careful pre-operative analysis of the patient's medical history to verify his or her suitability for the implant treatment. It is also recommended to collect and file all the clinical, radiological and radiographic records. After making models of the two arches, the best position and orientation of the chosen implants will be evaluated based on the occlusal plane and on a correct distribution of the forces. In this phase, a surgical stent may be created to guide the specialist to correctly position the implants during the operation. Depending on the specific case, a decision will be made on whether to use a single or double phase surgical procedure, using titanium cylinders (code DIM) to make the radiological/surgical stent.

A radiological and surgical stent can be made by using the special cylinders in titanium (code DIM), which can be used to obtain an ideal positioning of the implants in terms of biomechanics and aesthetics.

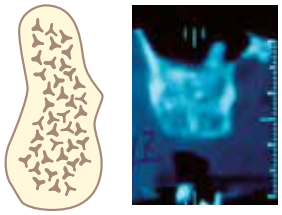
In addition to an oral examination, both clinical and with x-rays, it is recommended to take a CT scan of the interested area; once the x-rays and scans have been obtained, the specialist can identify the most suitable implant with the help of convenient transparent radiographic guides. The pre-operative study of the Dentalscan allows the identification of the type of bone present in the insertion point of the implant. The choice of the surgical procedure must take into consideration the type of bone present. The bone is normally classified into 4 types according to the density. The classification (according to Carl Misch) is the following:



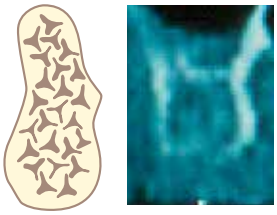
BONE D1: all cortical bone.



BONE D2: a core of bone marrow enclosed in a shell of cortical bone.



BONE D3: all bone marrow without cortical crest.

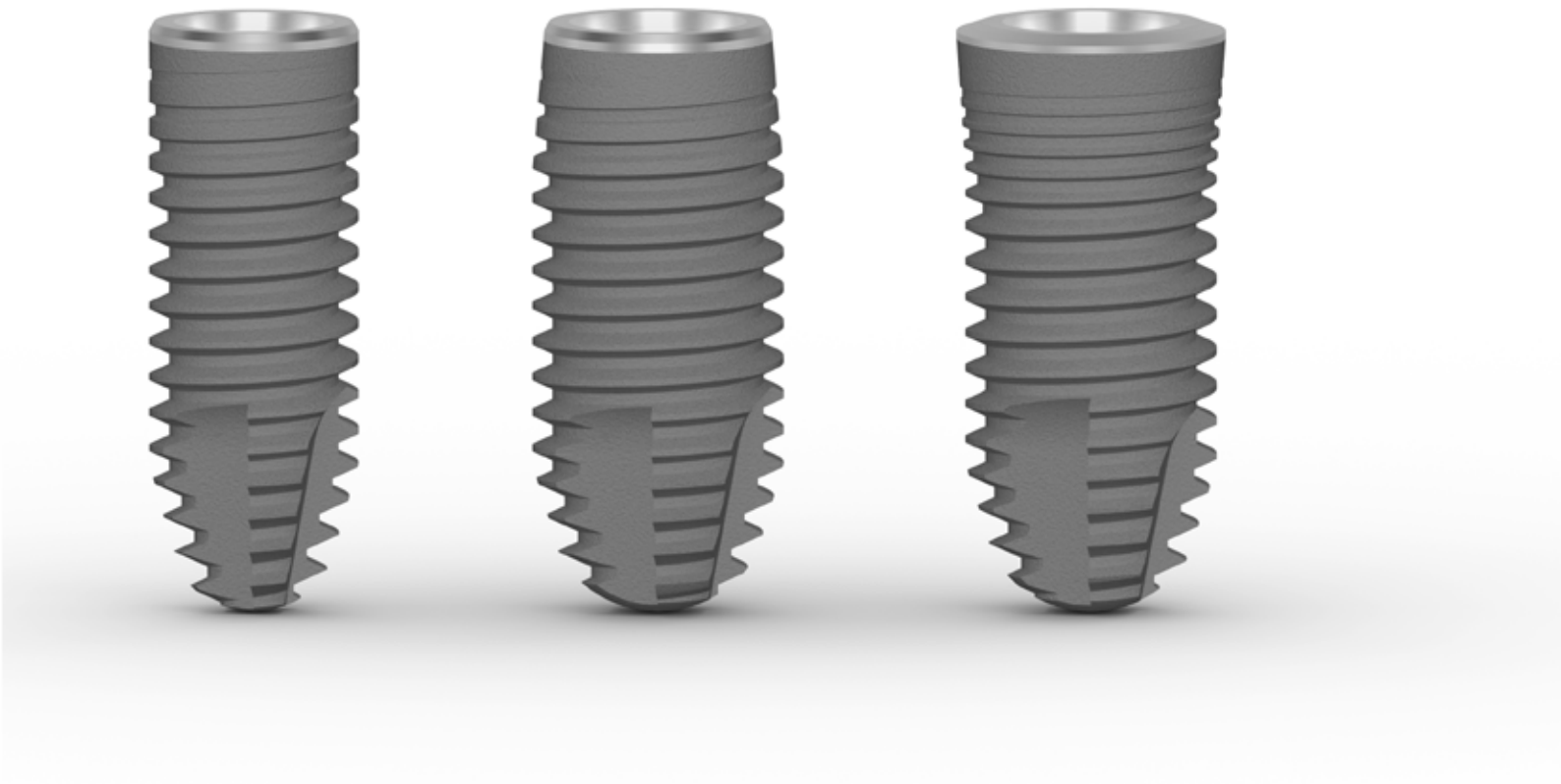


BONE D4: all bone marrow with very poor mineralization.

Dentalscan images courtesy of Dr. Marco Csonka - Catania

General indications

CSR implant fixtures are long-term implantable medical devices. All the fixtures are sold in single-use sterile packs. The function of the fixtures is to replace missing dental roots.
The fixtures have a connection in the crown part for receiving an implant post aimed at supporting a dental prosthesis. In implant-prosthetic rehabilitation with CSR implants, only original prosthetic components by Sweden & Martina must be used.
Use of non-original components limits the responsibility of Sweden & Martina S.p.A. and renders the product warranty void.
The implants have a hybrid morphology, they are screw-shaped with an external thread and have a conical internal connection for connecting the prosthetic components.
CSR implants can be inserted in both edentulous and post-extraction sites, either immediate (insertion of the implant at the same time as the removal of the tooth or root), or deferred (normally about 3 weeks between extraction and insertion of the implant fixture).
All the fixtures are sold complete with the respective surgical cover screw. Surgical cover screws are also medical devices that can be implanted surgically, designed to remain in the oral cavity for even more than 30 days. The surgical cover screws can also be sold individually.



Method of use

The methods of use can be divided into two main surgical techniques:
- **Two stages**: an initial "submerged" stage, with implant insertion, covering of the connection with a surgical cover screw, suturation and subsequent reopening of the mucous membrane 2–6 months later, followed by prosthesis insertion;
- **One stage**: implant insertion and closure of the connection with a healing abutment instead of a surgical cover screw. Alternatively, in the presence of suitable therapeutic indications, it can be loaded immediately with an appropriate temporary or permanent dental post, depending on the case.

Implants are inserted in the bone following surgical protocols that must be considered according to the quantity and quality of the receiving bone, the implant and the possible need for regenerative therapies. A site is created in the patient's bone at the position of the new tooth to be replaced or inserted, using a series of calibrated bone drills or other suitable instruments, such as bone expanders, bone profilers or similar.

The necessary conditions for the success of the implant are:
- the presence of a certain quantity of bone;
- good periodontal (gingival) support;
- the absence of bruxism (tooth grinding) and serious malocclusions;
- the presence of good occlusal balance (correct masticatory occlusal plane).

CSR implants have been tested in a wide range of clinical situations:
- standard operating procedures;
- immediate and early loading;
- post-extraction situations, even combined with immediate loading.

Generally, masticatory loading with a fixed prosthesis occurs at a second stage, after 2 to 3 months for the mandible and after 4 to 6 months for the upper jaw. In some cases, but not all, immediate loading of the implants is possible; to do this it requires good primary stability, with no mobility or movement limited to a few microns. The bone-implant interface must therefore be of the order of a few millimicrons, otherwise there is the risk of fibrous integration.
The clinical indication for choosing the CSR implant depends on the site in which the implant is to be inserted, on the anatomy of the receiving bone and on the technique chosen from among those mentioned above. The choice must be made exclusively by the doctor, who must have the suitable training and experience and must plan the prosthetic rehabilitations beforehand.
Sweden & Martina has conducted 5,000,000-cycle fatigue resistance tests on CSR implants. The implants passed the test. Fatigue tests are conducted according to the standards and evaluated further with finite element calculations.

Key to CSR implant codes

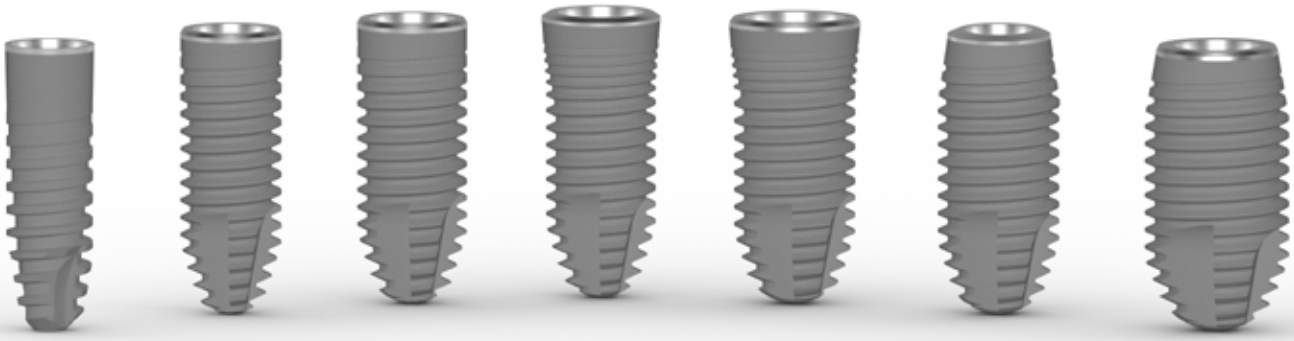
The implant codes are so-called "mnemonic" codes, i.e. they allow easy identification of the piece. Below is a table showing how the mnemonic codes work using **VSR-ZT-420RN-115** as an example:

implant type	surface	diameter	neck morphology	length
VSR	ZT	420	RN	115
VSR: CSR implant	**ZT:** ZirTi surface	**300**: 3.00 mm **350**: 3.50 mm **380**: 3.80 mm **420**: 4.20 mm **500**: 5.00 mm *It is the measure of the **endosseous diameter** of the implant taken in the middle third*	**ST**: Straight Neck **RN**: Reduced Neck Wide Neck*	**065**: 6.50 mm **085**: 8.50 mm **100**: 10.00 mm **115**: 11.50 mm **130**: 13.00 mm **150**: 15.00 mm **180**: 18.00 mm *Nominal length which expresses the endosseous length of the implant*

** Wide Neck CSR implants are not identified by a neck morphology code (e.g., VSR-ZT-380-100).*

CSR: the range

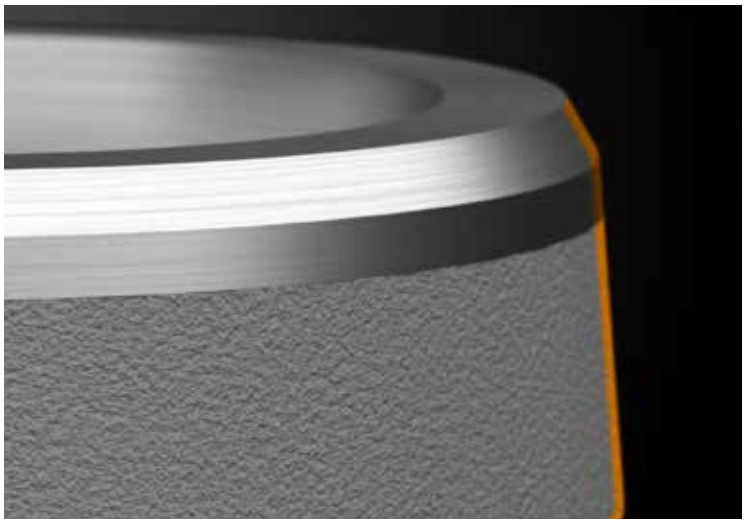
All implants of the CSR implant range have a **cylindrical morphology and full treated ZirTi surface**, with a **bevel in the most coronal portion**. CSR implants are available with **three different neck morphologies**, Wide Neck, Straight Neck and Reduced Neck, to meet different clinical needs.



STRAIGHT NECK			WIDE NECK		REDUCED NECK	
ø 3.00 mm	ø 3.50 mm	ø 3.80 mm	ø 3.80 mm	ø 4.20 mm	ø 4.20 mm	ø 5.00mm

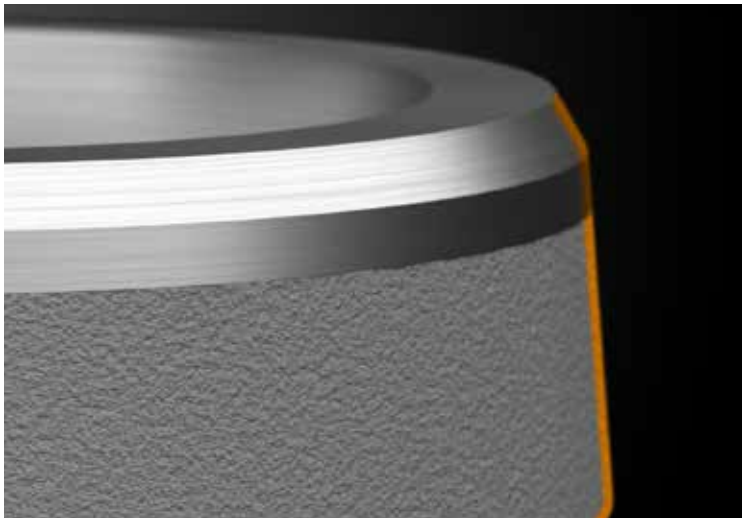
Range of heights

implant ø	heights
ø 3.00 Straight Neck	8.50, 10.00, 11.50, 13.00, 15.00 mm
ø 3.50 Straight Neck	6.50, 8.50, 10.00, 11.50, 13.00, 15.00, 18.00 mm
ø 3.80 Straight Neck	6.50, 8.50, 10.00, 11.50, 13.00, 15.00, 18.00 mm
ø 3.80 Wide Neck	6.50, 8.50, 10.00, 11.50, 13.00, 15.00, 18.00 mm
ø 4.20 Wide Neck	6.50, 8.50, 10.00, 11.50, 13.00, 15.00, 18.00 mm
ø 4.20 Reduced Neck	6.50, 8.50, 10.00, 11.50, 13.00, 15.00, 18.00 mm
ø 5.00 Reduced Neck	6.50, 8.50, 10.00, 11.50, 13.00 mm



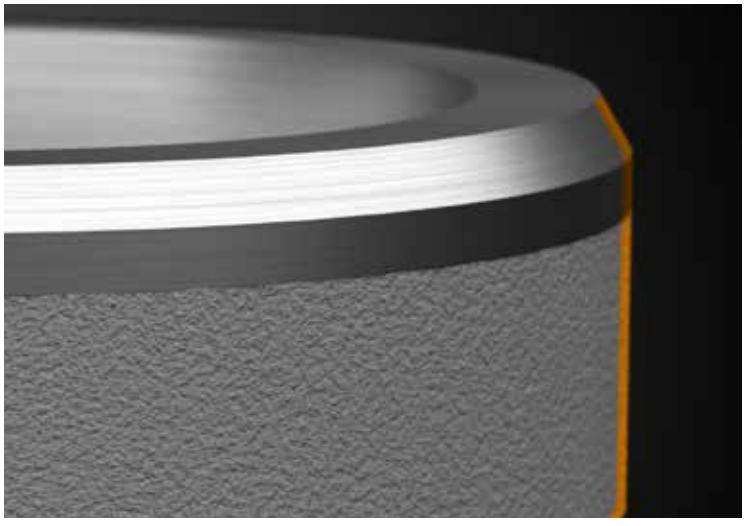
Straight Neck

Straight Neck implants have a straight, constant morphology throughout the entire body of the implant.



Reduced Neck

The convergent neck of the Reduced Neck implants provides more space at the crestal level, thus promoting bone growth.



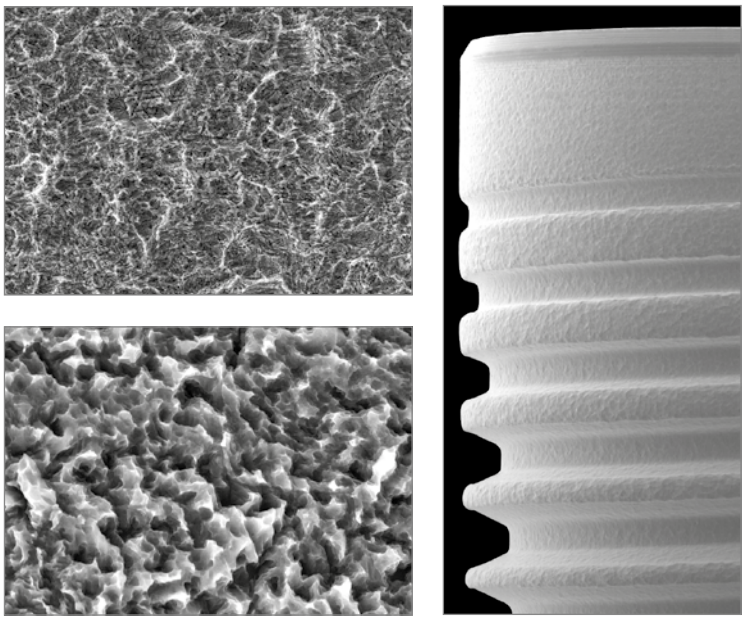
Wide Neck

The divergence at coronal level ensures stability at the coronal level even in low-density bone.

ZirTi surface

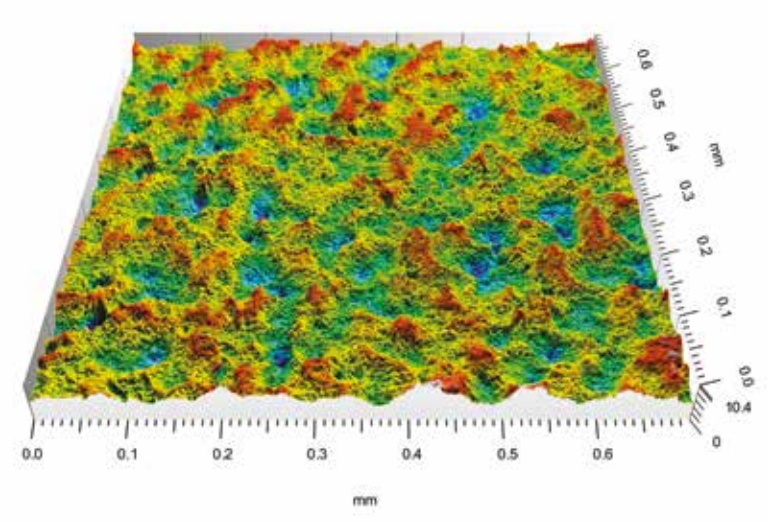
CSR implants are available with **full ZirTi treatment**.

Sand-blasting with zirconium oxide and etching with mineral acids give surfaces a characteristic micromorphology **capable of significantly increasing the bone-to-implant contact area and promoting osseointegration.**



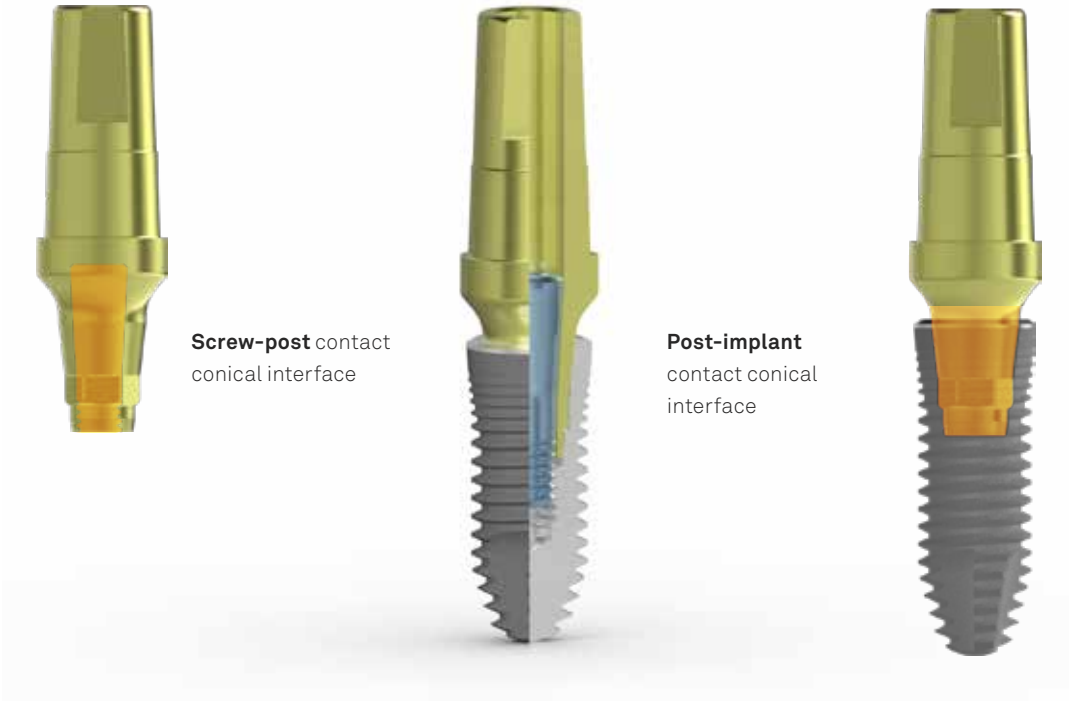
ZirTi surface magnified 2,000 and 10,000 times under scanning electron microscope.

Image of a portion of ZirTi surface obtained using a confocal microscope: the **micromorphology of the surface and the regularity of the picks** obtained with sand-blasting and acid-etching can be noted.



DAT conical connection

The **DAT (Double Action Tight) connection** is the most innovative feature of the CSR implant: a **double internal conical contact interface between the post and the implant** and between the screw and the post ensures an excellent seal against bacterial infiltration, protecting the bone from the risk of peri-implant infections that could affect a correct osseointegration and the consequent implant survival.

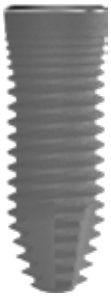


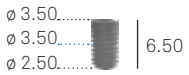
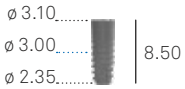
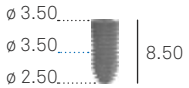
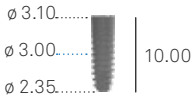
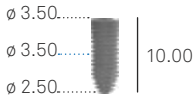
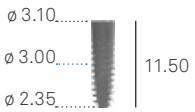
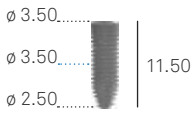
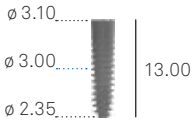
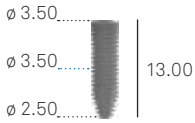
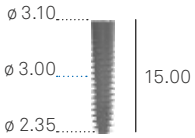
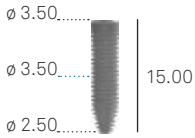
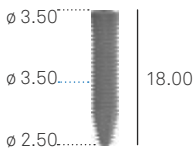
Screw-post contact conical interface

Post-implant contact conical interface

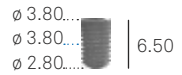
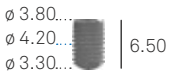
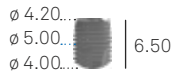
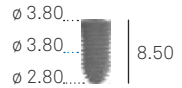
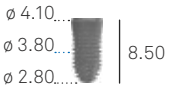
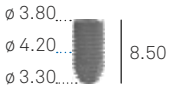
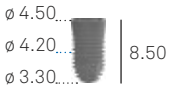
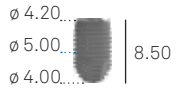
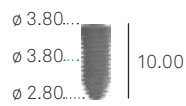
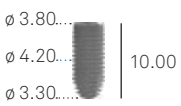
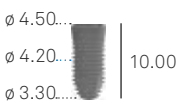
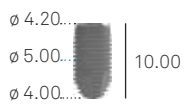
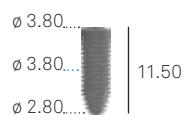
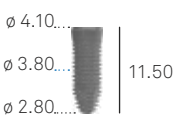
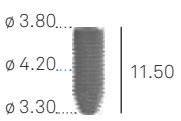
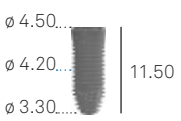
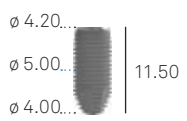
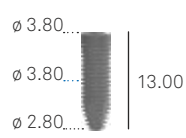
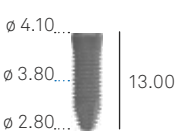
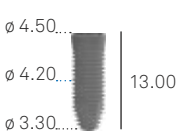
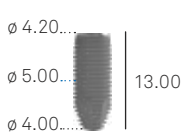
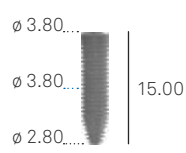
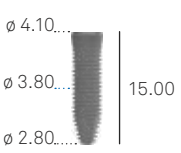
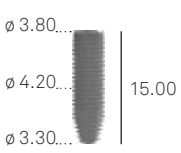
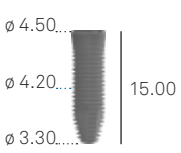
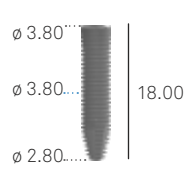
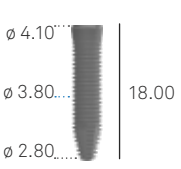
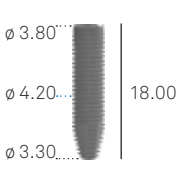
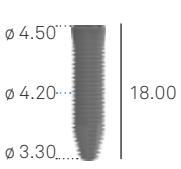
The **narrow-sized ø 3.00 and ø 3.50-mm implants** feature the DAT-N connection, that is the double conical interface connection in the narrow version, which provides the same benefits of the double conical interface, while maintaining a safety thickness such as to avoid any risk of unscrewing or disconnection.

Connection identification is made easy by the colour code, **bronze for the DAT-N connection and green for the DAT connection**. The colours bronze and green are used to identify the prosthetic components for taking the impression (transfers, analogs), the tissue conditioners and the extraction system for posts.

DAT-N connection		DAT connection				
ø 3.00 mm	ø 3.50 mm	ø 3.80 mm	ø 3.80 mm	ø 4.20 mm	ø 4.20 mm	ø 5.00mm
						
Straight Neck	Straight Neck	Straight Neck	Wide Neck	Wide Neck	Reduced Neck	Reduced Neck

DAT-N connection		
implant ø	3.00 mm	3.50 mm
neck	straight	straight
H 6.50 mm	-	**VSR-ZT-350ST-065** 
H 8.50 mm	**VSR-ZT-300ST-085** 	**VSR-ZT-350ST-085** 
H 10.00 mm	**VSR-ZT-300ST-100** 	**VSR-ZT-350ST-100** 
H 11.50 mm	**VSR-ZT-300ST-115** 	**VSR-ZT-350ST-115** 
H 13.00 mm	**VSR-ZT-300ST-130** 	**VSR-ZT-350ST-130** 
H 15.00 mm	**VSR-ZT-300ST-150** 	**VSR-ZT-350ST-150** 
H 18.00 mm	-	**VSR-ZT-350ST-180** 
Surgical cover screws	**VSR-VT-N** 	**VSR-VT-N** 

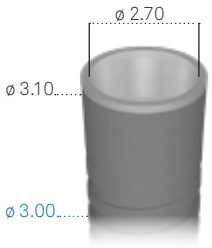
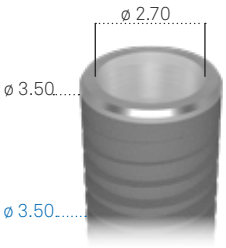
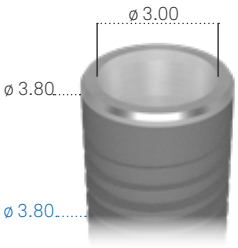
Each implant is sold with its own surgical cover screw.
Surgical cover screws are also available individually in sterile packs, and must be tightened to 8–10 Ncm.
See technical characteristics of Gr. 4 titanium on page 81.

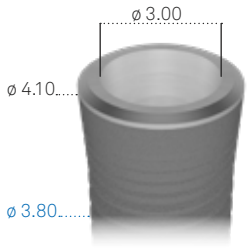
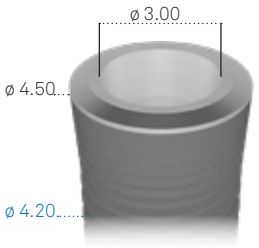
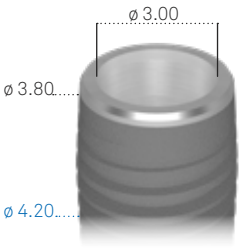
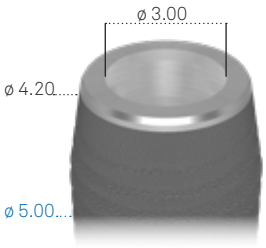
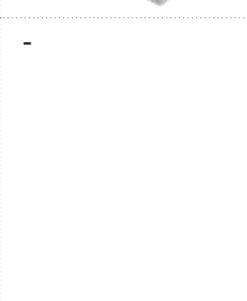
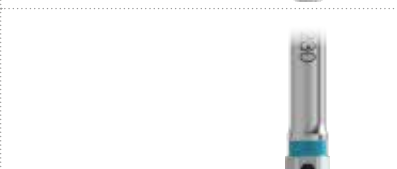
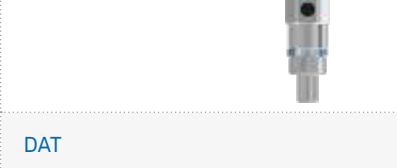
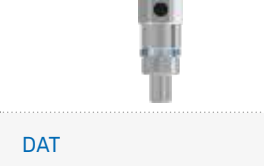
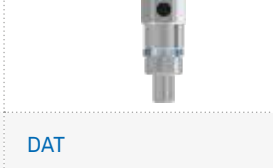
DAT connection					
implant ø	3.80 mm		4.20 mm		5.00 mm
neck	straight	wide	reduced	wide	reduced
H 6.50 mm	**VSR-ZT-380ST-065** 	**VSR-ZT-380-065** 	**VSR-ZT-420RN-065** 	**VSR-ZT-420-065** 	**VSR-ZT-500RN-065** 
H 8.50 mm	**VSR-ZT-380ST-085** 	**VSR-ZT-380-085** 	**VSR-ZT-420RN-085** 	**VSR-ZT-420-085** 	**VSR-ZT-500RN-085** 
H 10.00 mm	**VSR-ZT-380ST-100** 	**VSR-ZT-380-100** 	**VSR-ZT-420RN-100** 	**VSR-ZT-420-100** 	**VSR-ZT-500RN-100** 
H 11.50 mm	**VSR-ZT-380ST-115** 	**VSR-ZT-380-115** 	**VSR-ZT-420RN-115** 	**VSR-ZT-420-115** 	**VSR-ZT-500RN-115** 
H 13.00 mm	**VSR-ZT-380ST-130** 	**VSR-ZT-380-130** 	**VSR-ZT-420RN-130** 	**VSR-ZT-420-130** 	**VSR-ZT-500RN-130** 
H 15.00 mm	**VSR-ZT-380ST-150** 	**VSR-ZT-380-150** 	**VSR-ZT-420RN-150** 	**VSR-ZT-420-150** 	-
H 18.00 mm	**VSR-ZT-380ST-180** 	**VSR-ZT-380-180** 	**VSR-ZT-420RN-180** 	**VSR-ZT-420-180** 	-
Surgical cover screws	**VSR-VT** 	**VSR-VT** 	**VSR-VT** 	**VSR-VT** 	**VSR-VT** 

Each implant is sold with its own surgical cover screw.
Surgical cover screws are also available individually in sterile packs, and must be tightened to 8–10 Ncm.
See technical characteristics of Gr. 4 titanium on page 81.

Summary table

A colour code system placed on the implant pack has been defined for the CSR implant system to identify the endosseous diameter and the neck morphology.

implant ø	ø 3.00 mm Straight Neck	ø 3.50 mm Straight Neck	ø 3.80 mm Straight Neck
colour code on the pack	ST	ST	ST
Connection platform ø main dimensions			
final drill			
neck preparation drill			
Easy Insert driver			
connection	DAT-N	DAT-N	DAT
connection screw colour code	 M 1.6	 M 1.6	 M 1.8
transfer and implant analog colour code			

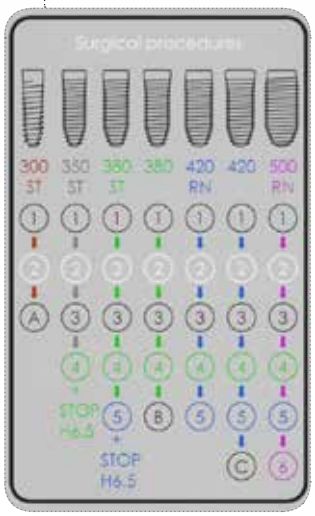
ø 3.80 mm Wide Neck	ø 4.20 mm Wide Neck	ø 4.20 mm Reduced Neck	ø 5.00mm Reduced Neck
			
			
		-	-
			
DAT	DAT	DAT	DAT
			
M 1.8	M 1.8	M 1.8	M 1.8
			

Surgical kit

The CSR surgical kit is designed for maximum simplicity of use and immediacy for the correct sequence of the instruments required. The instruments, all made of surgical stainless steel, have their descriptions screen-printed on the tray to allow the user to identify each instrument more easily and to put it back after the cleansing and cleaning phases, with the aid of a system of colour codes, numbers and letters that trace the suitable surgical procedures for the various implant diameters.
The surgical kits are supplied with X-ray templates for the graphic representation of all the CSR implant system measurements to allow choosing the most suitable implant diameters and lengths by means of radiographic or tomographic methods.

The compact dimensions of the case make it very practical for everyday use and transport

The kit contains a manual torque wrench for checking the implant insertion torque



The surgical sequences for the insertion of CSR implants are illustrated on the tray in a summary scheme consisting of:

- image of the implant to be inserted
- reference colour code of the implant diameter
- acronym identifying the morphology of the implant neck
- number and reference colour of the drills to be used
- letter of the countersink drill to be used if needed or any drill assembled with stop.

description	code
grommetless surgical kit containing the instruments necessary for CSR implants	**ZCSR-INT** 
Radel instrument grommetless tray for CSR instruments	**CSR-TRAY-INT** 

Important warning
The surgical kit also contains a non-sterile test implant that must not be used clinically, and can be easily recognized because it is entirely anodized in blue; it is recommended to use this implant for trials on models before starting to use implants clinically, so as to become familiar with the implant system and its respective instruments.

1 **Precision drill**
FS-230

2 **Pilot drill**
CSR-FP-200 ○

3 **Intermediate drill**
CSR-FI-280 ●

4 **Final drill ø 3.20**
CSR-FF-320 ●

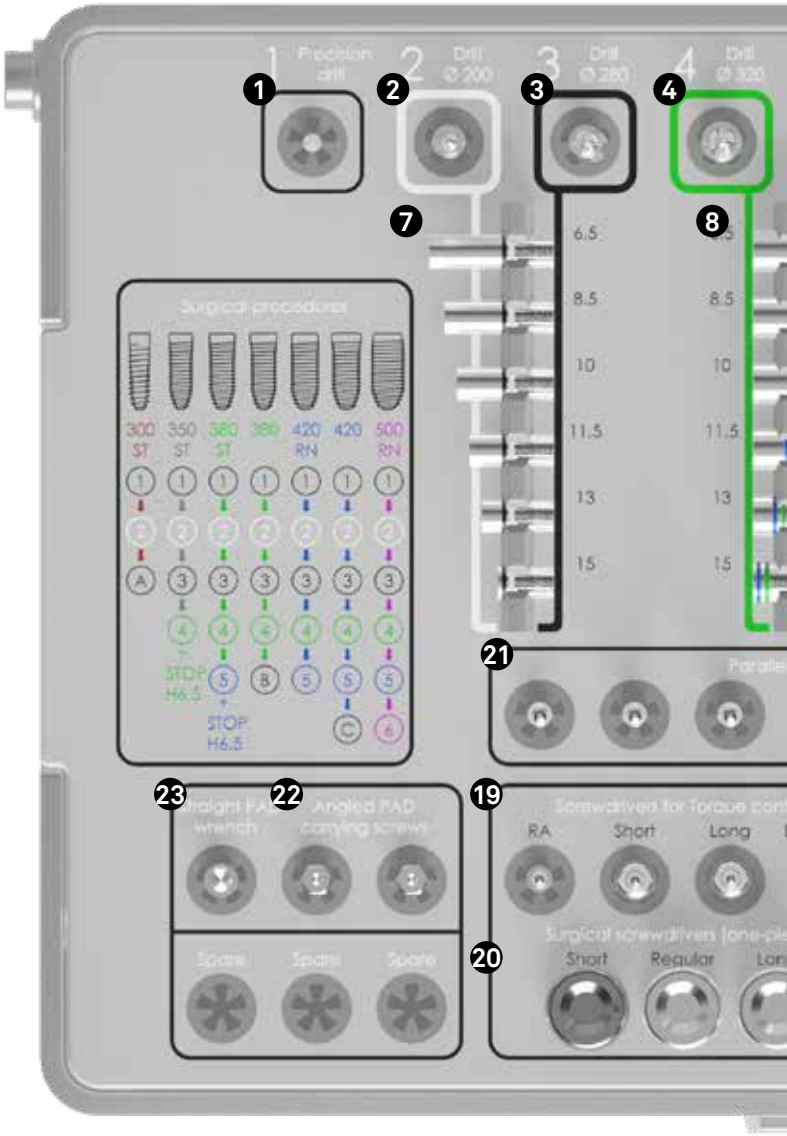
5 **Final drill ø 3.60**
CSR-FF-360 ●

23 **Screwdriver for straight P.A.D. abutments**
AVV2-ABUT

22 **P.A.D. transfer screw with manual tightening**
PAD-VTRAL-140-MAN

21 **Parallelism pins**
PP-2/28

20 **Digital surgical screwdrivers**
HSMXS-20-DG HSM-20-DG HSML-20-DG



19 **Prosthesic screwdrivers**
HSM-20-CA HSM-20-EX HSML-20-EX HSMXL-20-EX

18 **Easy Insert Driver Hex. 2.30 mm**
EASY4-EX230-EX EASYC4-EX230-CA EASYL4-EX230-CA

6

Final drill ø 4.40
CSR-FF-440 ●

7

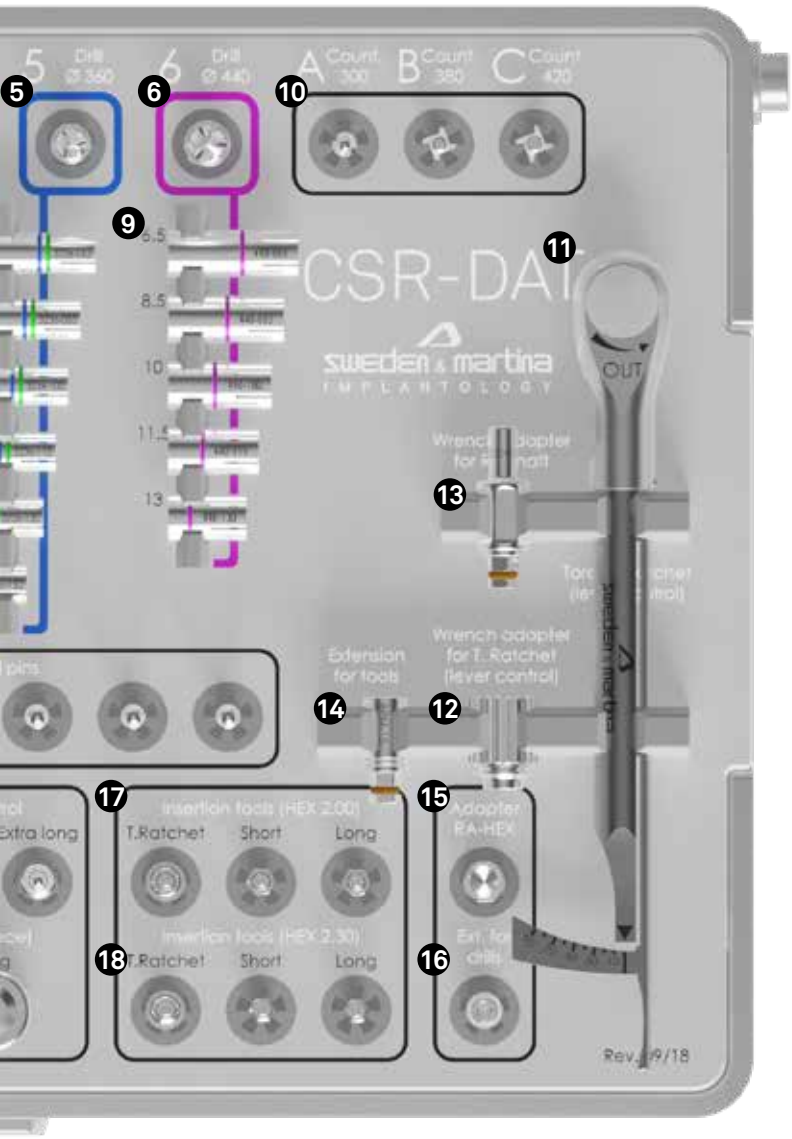
Pilot drill and intermediate drill stops
CSR-STOP-2028-065 ○●
CSR-STOP-2028-085 ○●
CSR-STOP-2028-100 ○●
CSR-STOP-2028-115 ○●
CSR-STOP-2028-130 ○●
CSR-STOP-2028-150 ○●

8

Drill stops ø 3.20 and ø 3.60 mm
CSR-STOP-3236-065 ●●
CSR-STOP-3236-085 ●●
CSR-STOP-3236-100 ●●
CSR-STOP-3236-115 ●●
CSR-STOP-3236-130 ●●
CSR-STOP-3236-150 ●●

9

Drill stops ø 4.40
CSR-STOP-440-065 ●
CSR-STOP-440-085 ●
CSR-STOP-440-100 ●
CSR-STOP-440-115 ●
CSR-STOP-440-130 ●



10

Countersink drills
FGS-200/300
CSR-FC-380
CSR-FC-420

11

Torque wrench
TWL

12

Torque wrench adaptor
TWL-AVV-EX

13

Adaptor
AVV-CA-DG-EX

14

Extension
BPM-15

17

Easy Insert Driver Hex. 2.00 mm
EASY4-EX200-EX EASYC4-EX200-CA EASYL4-EX200-CA

16

Extension for drills
PROF-CAL3

15

Adaptor
B-AVV-CA3

General indications

The surgical instruments designed for use with the implant systems manufactured by Sweden & Martina are reusable medical devices intended for temporary use in the oral cavity (no more than 60 minutes), re-usable. The functions of the surgical instruments are to prepare sites for Sweden & Martina implants, to insert the implants in the sites, to tighten and unscrew all the connecting screws (surgical cover screws, healing abutments, screws for posts, abutments, prosthesic screws, transfer screws, etc.).

The surgical instruments manufactured by Sweden & Martina are designed for use with dental implants manufactured by Sweden & Martina. Use of surgical instruments for operations with other implants than those manufactured by Sweden & Martina limits the responsibility of Sweden & Martina and renders the product warranty void. Sweden & Martina declines all responsibility for use of any non-original instruments. Sweden & Martina surgical instruments are sold in NON-STERILE packs.
Before use, they must be cleaned, disinfected and sterilized according to the instructions reported below. Failure to follow these warnings may expose the patient to infections.
The materials used for manufacturing the surgical instruments manufactured by Sweden & Martina were selected based on the properties indicated for their intended use according to directive 93/42, implemented in Italy with Law 46/97, Annex I – Essential Requirements, point 7.1.
Each packaging indicates the code, description of the contents and batch number. These same details, which are also indicated on the labels inside the packs, must always be provided by the practitioner in any relevant correspondence.

All the devices are identified by an instrument code, which is laser marked onto the body of each instrument. If there is not enough space to include the full code, the elements for unequivocally identifying the device (e.g. diameter or length) are provided. When handling the devices, both during use and during cleaning and sterilization procedures, it is recommended to use surgical gloves for personal protection from bacterial contaminations. Failure to follow these instructions may cause cross-infection.

Key to the implant codes: surgical instruments

The surgical instrument codes are so-called “mnemonic” codes that allows easy identification of the piece. Below is a table showing how the mnemonic codes work using various types of instruments as examples.

examples	component type and implant type	diameter	length
The range of instruments is vast, we indicate some examples of the main families of instruments.	The code CSR stands for the CSR implant system.	Normally it is the diameter of the implant or of the preparation for which the instrument should be used.	This measurement is normally linked to the height of the component, or to other important measurements that characterise it, or it is a code which defines the instrument shank.
CSR-FF-320	CSR-FF: final drill	3.20: for the preparation of the fixture with ø 3.80 mm	-
CSR-STOP-3236-065	CSR-STOP: stops for final drill	3236: for use with CSR-FF-320 and CSR-FF-360 drills	065: for implant with H 6.50 mm
PP-2/28	PP: parallelism pin	2/28: from 2.00 mm to 2.80 mm	-

Drills

All Sweden & Martina drills are made of **surgical steel** with **high resistance to corrosion and wear**. They are intended for mechanical use, i.e. they have a shank with a right angle attachment and must be used with a suitable micromotor. The extreme accuracy of design and production allows use **completely free from vibrations and oscillations**. However, incorrect insertion of the instruments in the handpiece will cause instrument vibration, eccentric rotation, early wear and shaft buckling. Suitable surgical micromotors only should be used. Micromotors should be checked regularly by their manufacturers, according to the indications given by the manufacturers, to prevent potential malfunctions (e.g. axle shifts for transmission shafts, worn or faulty forceps, etc.).

Failure to follow the instructions provided may cause surgical complications and consequent damage to the patient's health. It is recommended to use the rotation speeds indicated in the procedures on page 48 and following to prevent the development of bone necrosis. Lever movements increase the risk of instrument breakage and should therefore be avoided. Changes in speed should be avoided in general. Never apply pressure such as to force the instrument to stop rotating. This could lead to an excessive increase in heat in the tissues being drilled, with consequent bone necrosis, and damage both the instrument and the appliance used (micromotor). This could also lead to breakage of the instrument. Using an intermittent approach, with a back and forth movement in a vertical direction, prevents overheating and wear of the working part and an undesirable increase in the temperature in the tissues being cut. Suitable coolant should be used. Inadequate irrigation can lead to bone necrosis. Drill wear depends to a large extent on the type and density of the drilled bone: harder bone leads to greater instrument wear.
For greater safety and caution, given the device's capacity for resistance to wear, drills should not be used for more than 20 work cycles and should be replaced earlier if the instruments lose their cutting ability. These recommended **20 cycles** should be considered a rough guide. Always check the instrument's residual cutting capacity after each procedure. Sweden & Martina declines all responsibility in cases of excessively intense use. Never sharpen drills before use. Never use damaged, buckled or worn instruments.

Precision drill FS-230

The precision drill is made of surgical stainless steel. It is used to cut the cortical bone, so it is very sharp and pointed. The design of the blades ensures efficient cutting with both the tip and the edge. It has a maximum diameter of 2.30 mm. The laser marking at 4.80 mm indicates the maximum depth of insertion of the drill to obtain an adequate guide hole for subsequent drills.

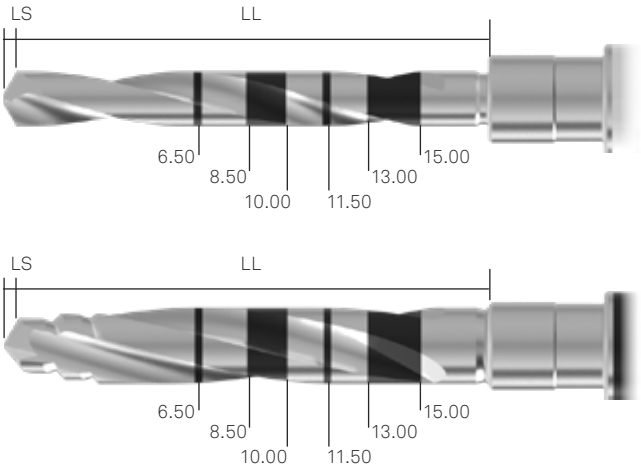
Important warning
The Precision drill is supplied with a protective silicone sheath to protect it during transport, and it must be removed before the first use. Since this drill is extremely sharp, special caution is required during handling.

Pilot and intermediate drill

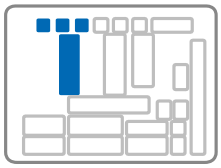
The pilot drill is cylindrical and has a diameter of 2.00 mm. It is designed for the preparation of the hole that will receive the implant and to serve as final drill when inserting CSR implants with a diameter of 3.00 mm. The pilot drill is easy to identify, thanks to the presence of a white ring and a laser-etched code on the drill shank. It has laser-etched depth marks and a spiral shape with two cutting edges. It must be used with abundant external irrigation.

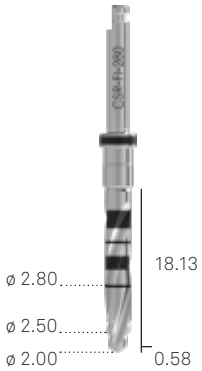
The intermediate drill is a drill with three cutting edges suitable for progressively widening the preparations in relation to the diameter of the drills to be used in succession.

LL: Total length of the working part, including the tip.
LS: Length of the tip. This measurement must be calculated in addition to the length of the preparation hole.



***Please note**: the drills always make a hole that is longer than the implant to be inserted.*
The oversizing (LS) is equal to the difference between the length of the working part of the drill and the nominal height of the implant.



pilot drill	intermediate drill
CSR-FP-200 	**CSR-FI-280** 

Pilot drill and intermediate drill stops

Stops are devices to be fitted in tip → shank direction on drills suited to receive them. They make it possible to restrict the working length of a drill to a pre-set height.
The same stop set is common to the pilot and intermediate drills, since the two share the same attachment: for this reason, the stops have a white and a black ring, referring to the two drills to use them with.

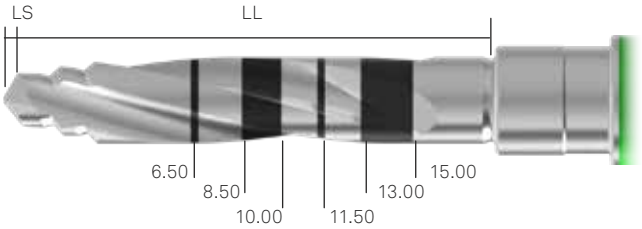
pilot drill and intermediate drill stops					
CSR-STOP-2028-065 stop 6.50 mm	**CSR-STOP-2028-085** stop 8.50 mm	**CSR-STOP-2028-100** stop 10.00 mm	**CSR-STOP-2028-115** stop 11.50 mm	**CSR-STOP-2028-130** stop 13.00 mm	**CSR-STOP-2028-150** stop 15.00 mm
					

It is recommended always to check that the stop is inserted at the desired height. Incomplete insertion may reduce the preparation height. Any insertion difficulties can be solved by loosening the stop tabs slightly, using forceps. It is also recommended to check the retention exerted by the stop, as if retention is too weak the instrument will fall off the drill during operation.
In the event of reduced retention capacity, simply tighten the tabs by hand or using forceps.

Final drills and related stops

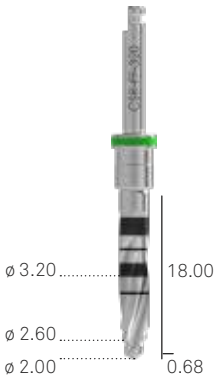
Made of stainless steel with high resistance to corrosion and wear, CSR final drills present a number of cutting edges proportional to the hole diameter, so as to allow a continuous and homogeneous cutting movement and better stability of the instrument during the surgical phases. All this allows to obtain high-precision implant preparations, with consequent easiness in inserting the implant. It is recommended to use these drills with the related depth stops, also included in the surgical kit.

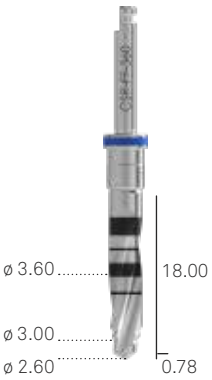
LL: Total length of the working part, including the tip.
LS: Length of the tip. This measurement must be calculated in addition to the length of the preparation hole.

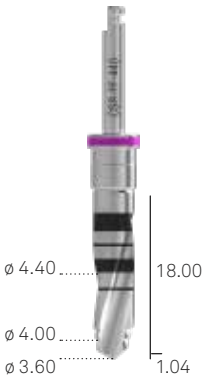


***Please note**: the drills always make a hole that is longer than the implant to be inserted.*
The oversizing (LS) is equal to the difference between the length of the working part of the drill and the nominal height of the implant.

implant ø	3.50 mm Straight Neck 3.80 mm Wide Neck	3.80 mm Straight Neck 4.20 mm Wide Neck 4.20 mm Reduced Neck	5.00 mm Reduced Neck
final drills	**CSR-FF-320**	**CSR-FF-360**	**CSR-FF-440**







drill code	CSR-FF-320	CSR-FF-360	CSR-FF-440
stop for preparations H 6.50 mm	**CSR-STOP-3236-065** 	Use CSR-STOP-3236-065	**CSR-STOP-440-065** 
stop for preparations H 8.50 mm	**CSR-STOP-3236-085** 	Use CSR-STOP-3236-085	**CSR-STOP-440-085** 
stop for preparations H 10.00 mm	**CSR-STOP-3236-100** 	Use CSR-STOP-3236-100	**CSR-STOP-440-100** 
stop for preparations H 11.50 mm	**CSR-STOP-3236-115** 	Use CSR-STOP-3236-115	**CSR-STOP-440-115** 
stop for preparations H 13.00 mm	**CSR-STOP-3236-130** 	Use CSR-STOP-3236-130	**CSR-STOP-440-130** 
stop for preparations H 15.00 mm	**CSR-STOP-3236-150** 	Use CSR-STOP-3236-150	-

It is recommended always to check that the stop is inserted at the desired height. Incomplete insertion may reduce the preparation height. Any insertion difficulties can be solved by loosening the stop tabs slightly, using forceps.
It is also recommended to check the retention exerted by the stop, as if retention is too weak the instrument will fall off the drill during operation. If the retention capacity of the stops is reduced, simply tighten the tabs by hand or using forceps.

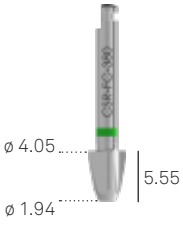
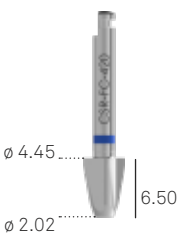
***Important note**: the CSR-FP-200 pilot drill is used for the insertion of ø 3.00 mm CSR implants, see previous pages*

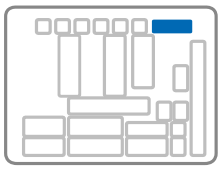
Countersink drills

The kit contains countersink drills that allow preparing the site for the neck of CSR implants in the presence of a very thick cortical bone. Countersink drills have a different morphology depending on the diameter and type of the neck to prepare. Each drill has to be used only for the implant of reference indicated in the table.

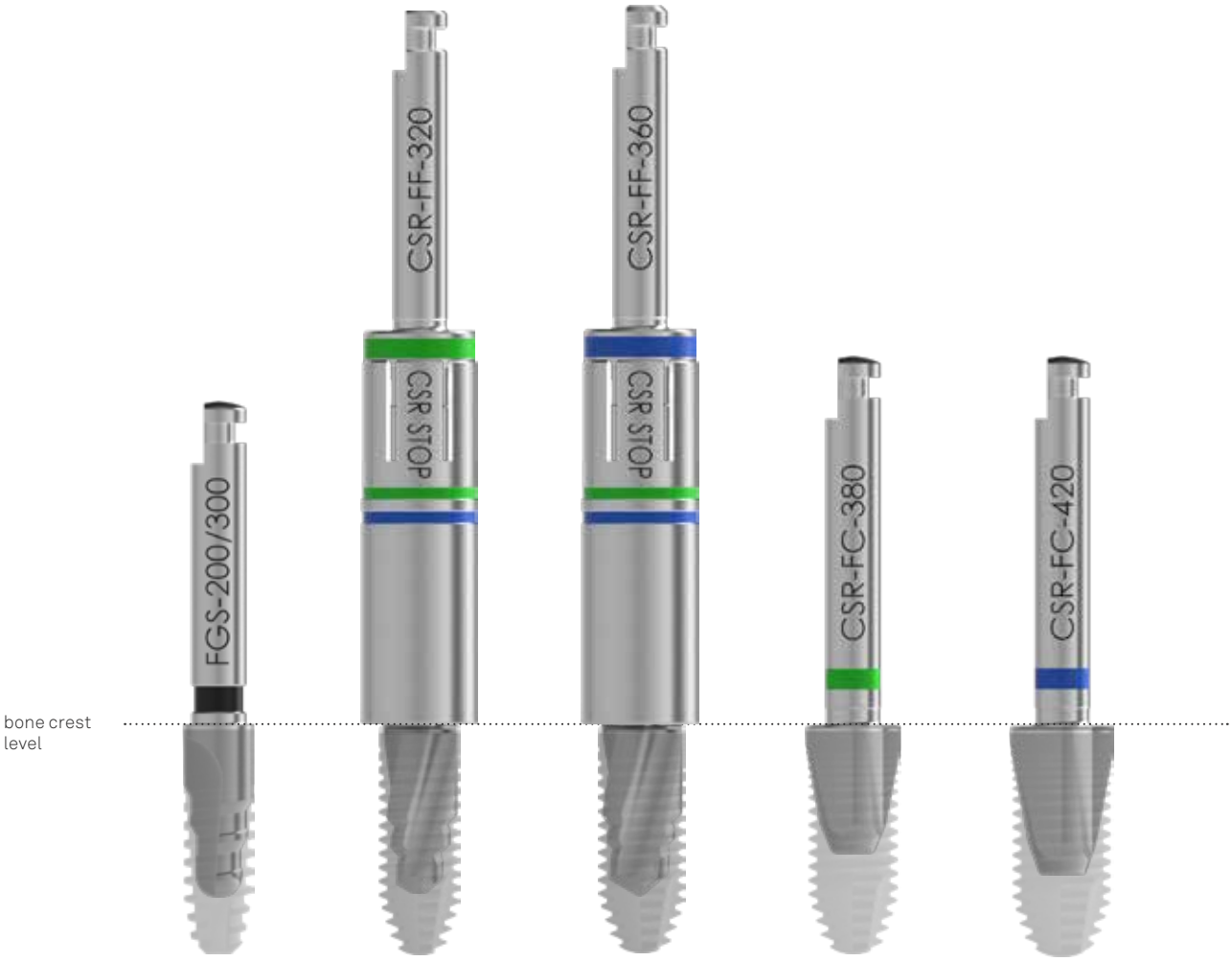
Coloured rings make it simple to recognize the instruments for each implant diameter

Drill FGS-200/300: dedicated to ø 3.00 mm implants

implant ø	3.00 mm Straight Neck	3.80 mm Wide Neck	4.20 mm Wide Neck
countersink drills for CSR implants	**FGS-200/300** 	**CSR-FC-380** 	**CSR-FC-420** 



The countersink drills, as shown in the image below, are used for ø 3.00 mm Straight Neck CSR implants and ø 3.80 and ø 4.20 mm Wide Neck CSR implants. For the neck preparation of ø 3.50 and ø 3.80 mm CSR Straight Neck implants, the CSR-FF-320 and CSR-FF-360 final drills attached to the CSR-STOP-3236-065 depth stop are used for preparations of H 6.50 mm.



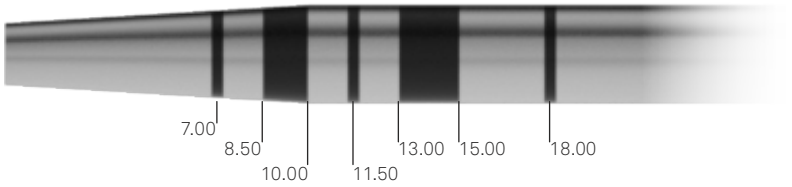
ø 3.00 mm Straight Neck	ø 3.50 mm Straight Neck	Ø 3.80 mm Straight Neck	Ø 3.80 mm Wide Neck	ø 4.20 mm Wide Neck

Osteotomes

A complete set of osteotomes, optionally available, has been designed for expansion protocols. The laser-etched codes on the handles indicate the osteotome diameter, to make it easier to recognize the correct surgical sequence. The laser marking on the point mark all the available heights. A practical universal instrument case for storing and organizing them is available.

description	Osteotome ø 0.20 flat tip	Osteotome ø 0.90 flat tip	Osteotome ø 1.60 concave tip	Osteotome ø 2.00 concave tip	Osteotome ø 2.40 concave tip
code	**E-OS-020-PP**	**E-OS-090-PP**	**E-OS-160-PC**	**E-OS-200-PC**	**E-OS-240-PC**
					

Osteotomes are optional instruments not included in the surgical kit, and can be ordered singularly for separate.

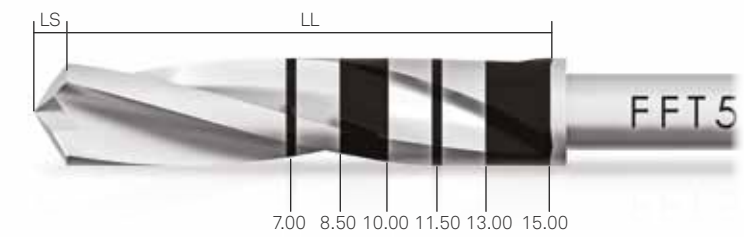


description	code
universal case in Radel for osteotomes can hold up to 12 instruments	**OS-TRAY** 

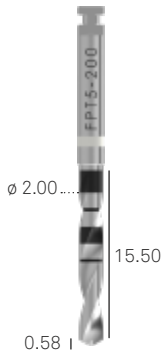
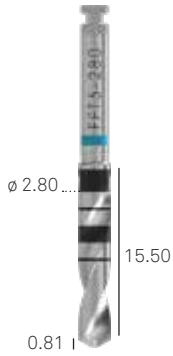
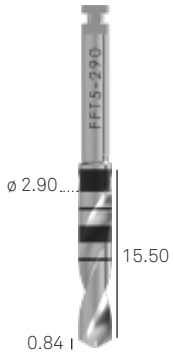
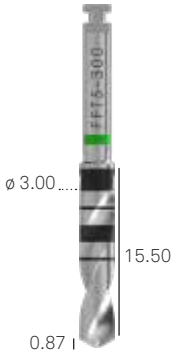
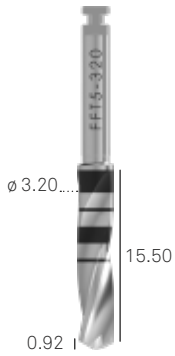
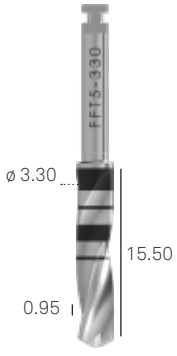
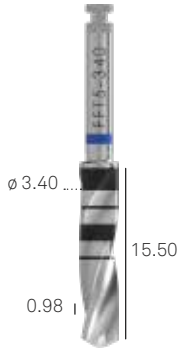
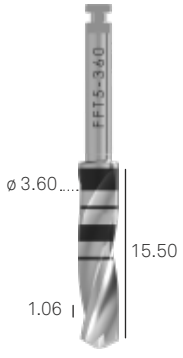
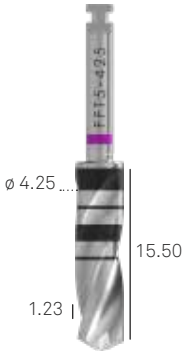
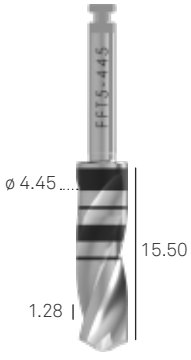
Drills for distal sectors

As an option, shorter drills are available that are very practical in distal sectors with limited oral opening. They come in a wide range of diameters and are also useful for preparations in extremely compact bone where, in the most coronal portion, it is desired to widen the preparation diameter by 0.10 mm with respect to the size of the standard drills to facilitate the insertion of the implants. On the other hand, in low-density bone they can be used to under-prepare the implant site so as to obtain optimum primary stability.

LL: Total length of the working part, including the tip.
LS: Length of the tip. This measurement must be calculated in addition to the length of the preparation hole.



***Important note**: The drills always make a hole that is longer than the implant to be inserted. The oversizing (LS) is equal to the height of the tip of the drill that is being used. See drawing on the side.*

drill ø	2.00	2.80	2.90	3.00	3.20
drills for distal sectors	**FPT5-200-LXS**	**FFT5-280-LXS**	**FFT5-290-LXS**	**FFT5-300-LXS**	**FFT5-320-LXS**
					
drill ø	**3.30**	**3.40**	**3.60**	**4.25**	**4.45**
drills for distal sectors	**FFT5-330-LXS**	**FFT5-340-LXS**	**FFT5-360-LXS**	**FFT5-425-LXS**	**FFT5-445-LXS**
					

** The drills for distal sectors are not included in any surgical kit and must be purchased separately. They cannot be used with depth stops.*

Easy Insert driver

CSR implants do not require a mounter device because they can be engaged directly inside the connection by practical **Easy Insert drivers**, designed **to guarantee a safe grip, to prevent deformations** to the corners of the connections and at the same time **to allow easy removal from the internal part of the implant connection**. The use of these drivers makes the surgical procedure of insertion extremely predictable.

Easy Insert for DAT-N connection

Easy orientation inside the connection thanks to the hexagonal visual indicator corresponding to the hexagon of the prosthesis and to black laser-etched dots on three faces

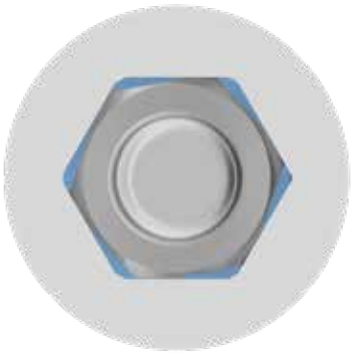
The whole is extremely **safe and reliable with the use of a special titanium o-ring that engages inside the connection**

The presence of a wide hexagon allows engaging the patented Easy Insert drivers **easily and safely for insertion of the implants** into the relative sites

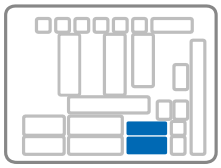
Easy Insert for DAT connection

The special patented design of Easy Insert drivers ensures that the faces (and not the corners) of the instrument make contact with the faces of the implant hexagon.

The dodecagonal design of the drivers **prevents deformations to the implant connection, thus guaranteeing extremely high prosthetic stability and precision**.



Peñarrocha-Oltra D., Rossetti P.H.O., Covani U., Galluccio F., Canullo L.,
Microbial leakage at the implant-abutment connection due to implant insertion maneuvers: cross-sectional study
Journal of Oral Implantology, 2015, 61(6);e292-e296, DOI 10.1563/aaid.joi.D.14.00235



When using the Easy Insert driver with the torque wrench with control lever or ratchet, as when using any other instrument for inserting implants with a dynanometric key, it is likewise advisable to take care to keep the working axis as perpendicular as possible. It is also fundamental for the movement performed with the ratchet during tightening to be slow and uniform, avoiding brusque movements as much as possible. If the precautions of use are not followed and the maximum torque is exceeded, the instrument could be broken: for this reason there is a default breaking point located over the dots, to allow the operator to remove the driver from the implant without any difficulties.
It is recommended to grip the ratchet in the part closest to the connection and to maintain a light and constant pressure with one finger, to allow greater stability during tightening.

description	code	implant ø	included in the kit
short driver with right angle shank for DAT-N connection	**EASYC4-EX200-CA** 	**3.00 - 3.50 mm**	**CSR**
long driver with right angle shank for DAT-N connection	**EASYL4-EX200-CA** 	**3.00 - 3.50 mm**	**CSR**
driver with dynamometric key connector for DAT-N connection	**EASY4-EX200-EX** 	**3.00 - 3.50 mm**	**CSR**
short driver with right angle shank for DAT connection	**EASYC4-EX230-CA** 	**3.80 - 4.20 - 5.00 mm**	**CSR**
long driver with right angle shank for DAT connection	**EASYL4-EX230-CA** 	**3.80 - 4.20 - 5.00 mm**	**CSR**
driver with dynamometric key connector for DAT connection	**EASY4-EX230-EX** 	**3.80 - 4.20 - 5.00 mm**	**CSR**

Maintenance and care of Easy Insert drivers

The Easy Insert drivers are supplied prefitted with specific titanium O-rings. Since they are mechanical components, the retainer rings are subject to wear over time and can lose their elasticity and functionality.
The O-rings cannot be replaced, but it is necessary to replace the instrument.
The Easy Inserts were tested to be good for 40 uses in the worst conditions of use. This limit may however be subject to variations, depending on conditions of use. It is however always recommended to check the correct functionality of Easy Insert drivers every time they are cleaned and sterilized.
For this reason, and to allow the practitioner to become familiar with the use of Easy Insert drivers, the surgical kit contains an untreated non-sterile “test implant”, which can be easily recognized because it is entirely anodized in blue.

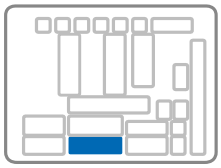
Important warning
It is recommended to use the Easy Insert drivers with a torque between 50 Ncm and 70 Ncm.
Thanks to tests performed on models, it has been observed that from 70 Ncm to 100 Ncm slight frictions between the instrument and the implant connection are possible, they can be avoided with a slight shaking movement of the Easy Insert in the connection. It is recommended not to exceed 80 Ncm for Easy Insert drivers with 2.00 mm hexagon and 140 Ncm for Easy Insert drivers with 2.30 mm hexagon. The implant insertion phase must be carried out with torque wrench with control lever TWL.

Drivers for fixation screws and extraction tools

The surgical kit contains several useful instruments for screwing and unscrewing the surgical cover screws, the transfer screws for posts, the abutments and more generally all the screws of the CSR system: the slightly conical coupling between the driver and the screw allows an appropriate retention when carrying the screw in the oral cavity. All the screwdrivers are made of stainless steel for surgical use.

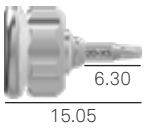
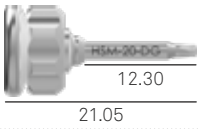
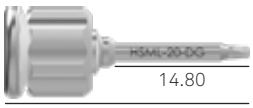
Important warning
Excessive torques can damage the internal threads of the fixation screws and the edges of the drivers and make it impossible to unscrew the conical screws, causing also severe intra-surgical and prosthetic complications. The recommended torque for the tightening of the different components are summarized in the following chart:

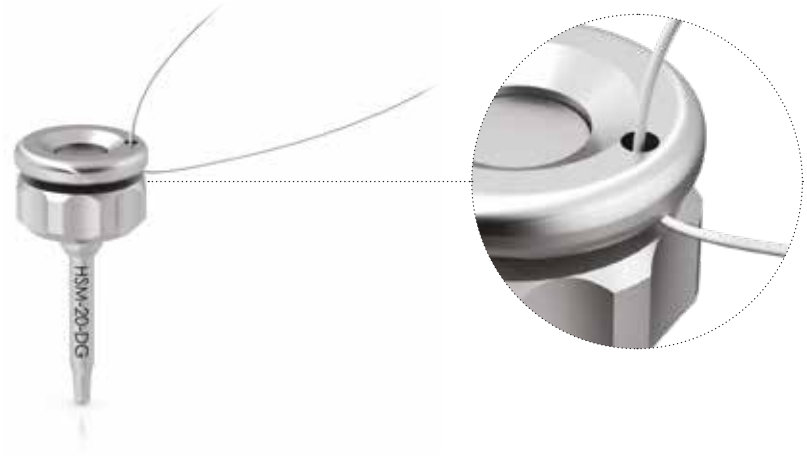
description	recommended torque
Surgical cover screws, healing abutments	8-10 Ncm
All prosthetic screws	20-25 Ncm
All prosthetic components screwed directly onto an implant	25-30 Ncm
Transfer fixation screws	8-10 Ncm



Surgical screwdrivers

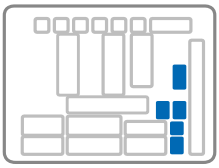
Their design makes them very practical in the surgical phases for the screwing of the surgical connecting screws and for the phases of uncovering and management of the healing abutments. They must not be used when working with definitive prostheses, as they do not allow tightening torque to be controlled.

description	code	included in the kit
screwdriver for surgical cover screws and fixation screws, digital, extra-short	**HSMXS-20-DG** 	**CSR**
screwdriver for surgical cover screws and fixation screws, digital, short	**HSM-20-DG** 	**CSR**
screwdriver for surgical cover screws and fixation screws, digital, long	**HSML-20-DG** 	**CSR**



Important warning
It is recommended to pass a thread through the hole on the top of the digital screwdriver to prevent it from falling.

Important warning
Lever movements should be avoided as they increase the risk of breakage. Before tightening, make sure the hex socket screw head on the driver tip is correctly inserted into the screws to be tightened. Incorrect insertion is likely to pare off the hexagonal connection of the screwdriver or the screw to be tightened.
Drivers have a slightly conical profile, able to guarantee the hexagonal connection on the tip of the driver grips inside the hexagonal connection on the head of the screws, making it possible to carry the screw to the patient's mouth correctly, without dropping it.
Replace drivers regularly to reduce the risk of wear to the hex connection.



Extensions and connectors

description	code	included in the kit
extension for drivers, bone taps, screwdrivers and manual drivers, with hexagonal connector for torque wrench	**BPM-15** 	**CSR**
extension for surgical drills	**PROF-CAL3** 	**CSR**
driver for right angle and manual instruments and instruments with hexagonal connection for ratchet	**B-AVV-CA3** 	**CSR**
screwdriver for right angle and manual instruments and instruments with hexagonal connection for torque wrench	**AVV-CA-DG-EX** 	**CSR**
adaptor for control lever TWL	**TWL-AVV-EX** 	**CSR**

Drivers for intraoperative removal of implants

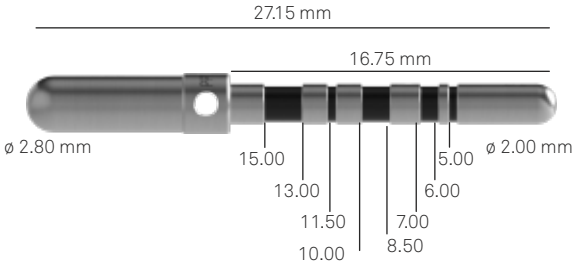
description	code	implant ø	included in the kit
short driver for DAT-N connection	**BC-EX200** 	**3.00 - 3.50 mm**	**Not included in the surgical kit, available separately**
long driver for DAT-N connection	**BC-EX200** 	**3.00 - 3.50 mm**	**Not included in the surgical kit, available separately**
short driver for DAT connection	**BC-EX230** 	**3.80 - 4.20 - 5.00 mm**	**Not included in the surgical kit, available separately**
long driver for DAT connection	**BC-EX230** 	**3.80 - 4.20 - 5.00 mm**	**Not included in the surgical kit, available separately**

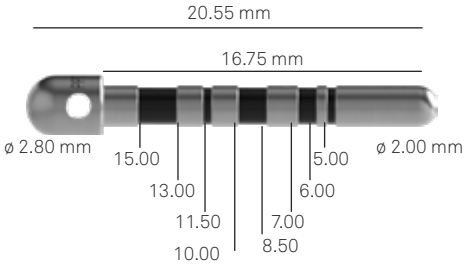
Parallelism pins

Parallelism pins can be used to check the insertion axis of the implants and the parallelism between more fixtures. They have one side with diameter ø 2.00 mm and the other ø 2.80 mm, so as to be used after the drills with the same diameter.

description	code
parallelism pin with a ø 2.00 mm side and a ø 2.80 mm	**PP-2/28** 

Parallelism pins with depth notches allow the control of the preparation height during the first surgical step, thanks to the notches provided on the side with a diameter of ø 2.00 mm. As the notches have a slightly smaller diameter than the body of the pin, they can be clearly noted on intraoperative X-rays. The other side of the pin has a diameter of 2.80 mm and it has a hole in which a safety thread can be inserted. The small version of the pin, the one with a shorter ø 2.80 side, is useful for patients with limited oral opening or for its use in distal sectors.





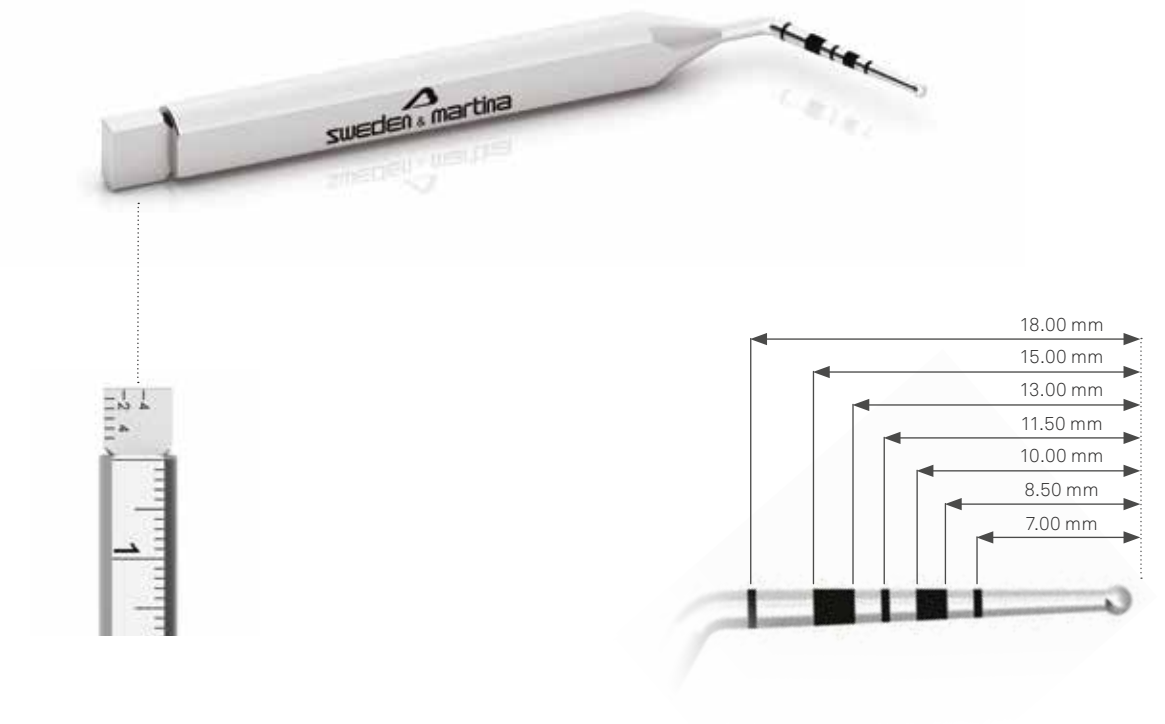
description	code
parallelism pin with depth lines, large*	**PPTL-2-28** 
parallelism pin with depth lines, small*	**PPTS-2-28** 

Important warning
It is recommended to pass a thread through the hole in the center of the pin to prevent it from falling.

**Optional instruments, not included in the surgical kit*

PROF3 depth gauge

It is a practical instrument which allows to verify the depth of the preparation holes and the distance between the implants. It is not included in any surgical kit, it can be ordered separately.

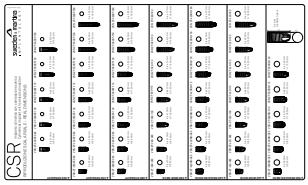
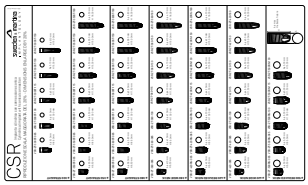
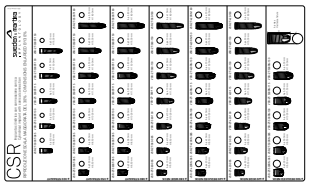


Spare O-ring

description	code	included in the kit
kit with 5 spare o-rings for all accessories with hexagonal connection for dynamometric key	**ORING180-088**	**Not included in the surgical kit, available separately**

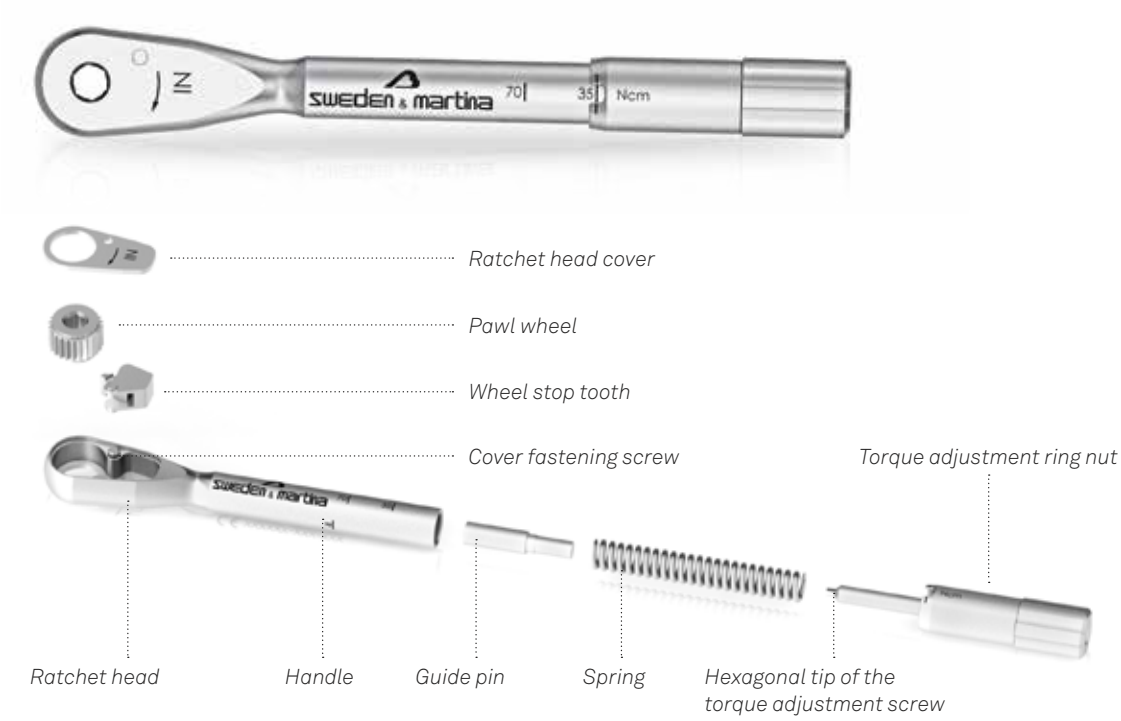
X-ray templates

The surgical kits are supplied with X-ray templates for the graphic representation of all the implant measurements to allow choosing the most suitable implant diameters and lengths by means of radiographic or tomographic methods. The templates are available in three versions: in real dimensions, increased of 20% and 30%.

description	code	included in the kit
X-ray template for CSR implants, real dimensions	**CSR-L100** 	**CSR**
X-ray template for CSR implants, dimensions increased by 20%	**CSR-L120** 	**CSR**
X-ray template for CSR implants, dimensions increased by 30%	**CSR-L130** 	**CSR**

Torque control ratchet CRI5-KIT

In addition, a special ratchet (CRI5-KIT) is available, with its own adjustment key, for quickly screwing the torque adjustment ring nut, and with gel lubricant for maintenance. The ratchet may be used with torque adjustment from 10 to 70 Ncm or in a blocked position without torque control. When using as a prosthetic ratchet for fastening the screws, refer to the torque values indicated in the table at page 32. The CRI5 dynamometric key is a multipurpose instrument that can be dismantled, and it is sold as non-sterile.



Before each use, this instrument must be cleaned and sterilized according to the instructions on page 44. Adequate maintenance, performed following in detail all the step by step instructions for the disassembly and correct reassembly of the device during cleaning operations, is essential for the correct functioning of the device and for its durability. Personnel who use this tool must be suitably trained, and they must have read the instructions in this manual prior to handling the device. After sterilisation, the ratchet is ready for use. The instrument must be tested for correct assembly and correct funcionality every time it is used, whether for surgical and prosthetic procedures.

The torque is adjusted by aligning the marking of the desired torque in the circular opening of the handle. The “IN” arrow legible on the top of the head indicates the screwing position of the key. The “OUT” arrow legible on the top of the head indicates the loosening or unscrewing position. An unlimited torque position is obtained by positioning the torque adjustment device up to the line marked “R” on the handle of the ratchet body.

The ring nut may be screwed and unscrewed by hand, but to speed up these operations the kit also contains a driver that allows it to be turned quickly. Any deterioration of the screwing, insertion and torque mechanisms must be checked by personnel responsible for the use and maintenance of this dental instrument. The pieces of this mechanism are not interchangeable; one piece from one key cannot be replaced by a piece from another key as each ratchet is calibrated INDIVIDUALLY. If a piece is lost, please return the instrument to Sweden & Martina for repair. No components for assembling the ratchet can be sold individually. Failure to follow the instructions provided may cause problems of maintenance and stability of the prosthesis.

Important warning

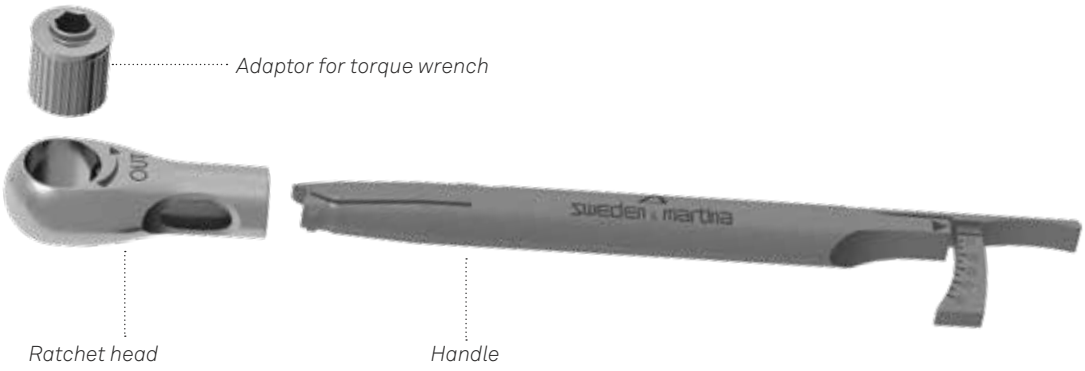
Torque is always adjusted by screwing in/unscrewing the sleeve at the end of the instrument handle. Torque must always be adjusted upwards, starting from a value lower than that required and tightening the adjustment sleeve in a clockwise direction until the desired value is reached. This means that if a torque value lower than that used previously is to be set, the adjustment sleeve must be slackened by two whole turns beneath the new torque value required, and then tightened again in a clockwise direction to the desired value.

In order to set a torque value, turn the ring nut in the clockwise direction until the wanted value.

To turn down a torque value of work of the ratchet, first it is necessary to unscrew the ring nut in the anticlockwise direction until reaching a value inferior of the wanted one, then proceed with the clockwise direction screwing until the chosen torque.

Torque wrench with control lever TWL

The surgical kit of the CSR implant system includes a special torque wrench with control lever (TWL). The torque wrench can be used to indicate the value of the torque applied during the surgical phases of screwing and unscrewing, showing values from 10 to 90 Ncm. It is supplied complete with a specific adaptor that allows it to be used with surgical instruments with a hexagonal connection.
The torque wrench with control lever TWL is a multipurpose instrument that can be dismantled, and it is sold as non-sterile.



Every time this instrument is used, it must first be cleaned and sterilized following the instructions on page 42.
Adequate maintenance, carried out by scrupulously following all the steps indicated for dismantling and reassemblying of the torque wrench during cleaning operations is essential for its correct use and to prolong its shelf life. The personnel using this instrument must be suitably trained and must have read the instructions given in this manual before proceeding with any operations with it.

After sterilization and before use, check that the first mark on the scale is aligned with the arrow. The instrument must be tested for correct assembly and correct funcionality every time it is used.

Important warning
The arm of the torque wrench must not move beyond the end of the scale, as this could lead to inaccurate torque readings.

The torque wrench can also be used as a fixed key, without using the scale, by using the entire handle as a lever. In this case, it must not exceed the torque value of 150 Ncm.
The personnel responsible for the use and maintenance of this instrument must check it for possible signs of deterioration of the tightening, insertion and torque mechanisms.
The single components of the torque wrench are not interchangeable, and it is not possible to use a component from one key to replace a component on another. If any component of the torque wrench is lost, always return the entire instrument to Sweden & Martina S.p.A. for all necessary repairs. Components for the assembly of the torque wrench with control lever are not sold individually. Failure to respect the instructions given may cause aesthetic problems and be damaging for the patient's health.

Cleaning, disinfection, sterilization and storage of the kit and of the surgical instruments

Attention! All the surgical instruments for dental implants are sold in non-sterile packs. Before use, they must be cleaned, disinfected and sterilized according to the following procedure validated by Sweden & Martina. These processes must be performed before use and before each subsequent reuse. Repetition of the processes described in this paragraph has minimal effect on the wear of these devices.

Instruments should always be checked before use to ensure they are in good working order. Any instruments showing signs of wear must be immediately replaced with new devices. It is particularly important to check that the drivers grip properly inside the engagement wells on the heads of the screws to be lifted and tightened with the same. Failure to follow these instructions may cause cross-infections and intraoperative complications.

a. Cleaning
Containers and transport to be used for washing: there are no special requirements. In case of automated cleaning: use an ultrasound bath with a suitable detergent solution. Use neutral detergents only. Follow the manufacturer's instructions concerning concentrations and washing times. Use demineralised water to prevent the formation of stains and marks. When draining, check the recesses of the devices, holes, etc. to make sure all residues have been completely removed. If necessary, repeat the cycle or clean manually.

When cleaning manually: use a suitable, neutral detergent and follow the manufacturer's user instructions. Brush the products with a soft-bristled brush under plenty of running water. Use the brush to apply the detergent to all surfaces. Rinse with distilled water for at least four minutes. Make sure plenty of running water passes through any holes. For drills with internal irrigation, use the special pins provided with the handpieces to ensure that the irrigation holes are completely clean and free of bone fragments or biological tissues. After rinsing, dry the devices thoroughly and place them inside suitable sterilisation bags. Do not exceed 120°C when performing a drying cycle in a washing and disinfection appliance.

b. Sterilization
In a vacuum autoclave, sterilizing as follows:
• autoclave (gravity displacement cycle) at a temperature of 121°C with a minimum autoclave cicle of 30 minutes and a drying cycle of 15 minutes;
• autoclave (dynamic air removal cycle) at the temperature of 132°C with a minimum autoclave cicle of 5 minutes and a drying cycle of 20 minutes.

c. Storage
After sterilization, the product must remain in the sterilization bags. The bags should only be opened immediately prior to reuse. In normal conditions, sterilization bags maintain the sterility of the contents, unless the wrapping is damaged. Therefore, do not use components if the bags in which they were kept are damaged, and resterilize in new bags before using them again. The storage time of products sterilized inside the bags should not exceed that recommended by the manufacturer of the bags. The product must be stored in a cool dry place, away from sunlight, water and sources of heat.

Cleaning, disinfection, sterilization and storage of the dynamometric key CRI5-KIT

The processes described below must be performed before use and before each subsequent operation. Repetition of the processes described in this paragraph has minimal effect on the wear of the device. The failure to follow these instructions may cause cross-infections. Containers and transport to be used for washing: there are no special requirements. As soon as possible after each use, the key must be placed in a container filled with a disinfecting/cleansing solution and covered with a cloth. This prevents the desiccation of the contaminating agents coming from the patient, and dissolves them, thus making cleaning easier and more effective. Completely disassemble the key as shown below:

Completely unscrew the torque adjustment screw and remove the spring inside the handle of the ratchet body. Do not separate the spring from the pin that acts as a stop.

Use the hexagon tip at the bottom of the torque adjustment screw to unscrew and completely remove the connecting screw of the cover from the side marked “OUT”. Exert a light pressure in order to avoid damaging the hexagon tip.

After removing the cover, pull out the two components contained inside the ratchet head: the toothed pawl wheel and wheel stop tooth.

In case of manual cleaning, clean the outer and inner surfaces of the instrument mechanically under hot water with a soft bristled brush. Inject hot water using a needleless syringe to wash the hard-to-access holes of the head and the area around the pawl wheel and wheel stop. If necessary, proceed in the same way for the inside of the handle and of the torque adjustment device. Use a suitable, neutral detergent and follow the manufacturer’s user instructions. Use the brush to apply the detergent to all surfaces. Rinse with distilled water for at least four minutes. Make sure the running water passes abundantly through the passages. In case of automated ultrasound cleaning: use an ultrasound bath with a suitable detergent solution.
Use neutral detergents only. Follow the manufacturer’s instructions concerning concentrations and washing times. Use demineralised water to prevent the formation of stains and marks. During this cycle, avoid contact between the pieces because this causes the machined surfaces to deteriorate, and consequently, loss of precision of the torque measurement. When draining, check the recesses of the devices, holes, etc. to make sure all residues have been completely removed. If necessary, repeat the cycle or clean manually.
Observation: residual blood or other deposits reduce the sterilization’s effectiveness which is why it is important to perform thorough cleaning. During cleaning, avoid sprays or jets of liquid and adopt adequate protections. Avoid contact between this instrument and other nickel-plated instruments.

Components must be reassembled before sterilization. Dry the parts, lubricate the functional areas lightly and reassemble the key as shown in the figures.
Too much lubrication may cause the surfaces of the instrument to resurface during sterilization. Use only the lubricant supplied.

After lubricating the parts shown in the figure, insert the two elements of the ratchet head acording to the following sequence: the toothed pawl wheel and then the wheel stop tooth.

Lubricate the contact areas between the tooth of the pawl wheel and the pin of the wheel stop tooth.

Once parts 2 and 3 have been lubricated and inserted in the head of the ratchet body, position the cover and turn the ratchet body from the “OUT” side. Tighten the screw with the hexagon tip of the torque adjustment screw.

Lubricate the spring inside the ratchet handle as shown in the figure. Assemble the torque adjustment screw, making sure the instrument functions properly. Manually activate the pawl wheel.

Sterilization: in a vacuum autoclave, proceeding as follows:

- autoclave (gravity displacement cycle) at a temperature of 121°C with minimum exposure of 30 minutes and drying cycle of 15 minutes.

This procedure is important in order to preserve the precision of the instrument within a tolerance of ± 3.5 Ncm. Operate the torque and insertion mechanism to check their proper functioning. Remove any traces of lubricant from the outer surface of the key. Place the device in a suitable sterilization bag. It is recommended to practice the disassembly and reassembly operations, following the instructions.

Cleaning, disinfection, sterilization and storage of the torque wrench with control lever TWL

The processes described below must be performed before use and before each subsequent operation. Repetition of the processes described in this paragraph has minimal effect on the wear of the device. The failure to follow these instructions may cause cross-infections.

a. Cleaning
Containers and transport to be used for washing: there are no special requirements. As soon as possible after each use, the key must be placed in a container filled with a disinfecting/cleansing solution and covered with a cloth.
This prevents the desiccation of the contaminating agents coming from the patient, and dissolves them, thus making cleaning easier and more effective.

Completely disassemble the key as shown below:

Press the driver and remove it from the head of the torque wrench, then remove the head by pressing inside the hollow, and delicately pull it out. The three separate components are now ready for cleaning.

In case of manual cleaning, clean the outer and inner surfaces of the instrument mechanically under hot water with a soft bristled brush. Use a suitable, neutral detergent and follow the manufacturer's user instructions. Use the brush to apply the detergent to all surfaces. Rinse with distilled water for at least four minutes. Make sure the running water passes abundantly through the passages. In case of automated ultrasound cleaning: use an ultrasound bath with a suitable detergent solution. Use neutral detergents only. Follow the manufacturer's instructions concerning concentrations and washing times. Use demineralized water to prevent the formation of stains and marks. During this cycle, avoid contact between the pieces because this causes the machined surfaces to deteriorate, and consequently, loss of precision of the torque measurement.

When draining, check the recesses of the devices, holes, etc. to make sure all residues have been completely removed. If necessary, repeat the cycle or clean manually.
Observation: residual blood or other deposits reduce the sterilization's effectiveness which is why it is important to perform thorough cleaning. During cleaning, avoid sprays or jets of liquid and adopt adequate protections. Avoid contact between this instrument and other nickel-plated instruments.

Components must be reassembled before sterilization.

This procedure is important in order to preserve the precision of the instrument within the following tolerances:

10 Ncm	± 0,75 Ncm
30 Ncm	± 1,5 Ncm
50 Ncm	± 2,5 Ncm
70 Ncm	± 3,5 Ncm
90 Ncm	± 4,5 Ncm

After cleaning, connect the torque wrench head to the body, pushing the components together and rotating them in opposite directions until a click is heard.

Press the driver into the torque wrench until a click is heard. The arrow on the torque wrench head indicates the direction of operation.

Place the device in a suitable sterilization bag. Disassembly and reassembly operations must be carried out following the indications provided here.

b. Sterilization

In a vacuum autoclave, proceeding as follows:

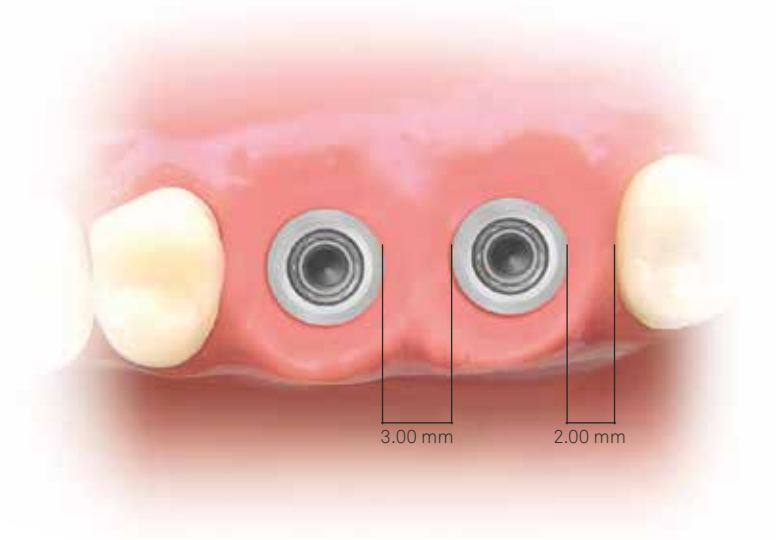
- autoclave (gravity displacement cycle) at a temperature of 121°C with a minimum autoclave cycle of 30 minutes and drying cycle of 15 minutes;
- autoclave (dynamic air removal cycle) at the temperature of 132°C with a minimum autoclave cycle of 4 minutes and drying cycle of 20 minutes.

c. Storage

After sterilization, the product must remain in the sterilization bags.
The bags should only be opened immediately prior to reuse. In normal conditions, sterilization bags maintain the sterility of the contents, unless the wrapping is damaged. Therefore, do not use components if the bags in which they were kept are damaged, and resterilize in new bags before using them again.
The storage time of products sterilized inside the bags should not exceed that recommended by the manufacturer of the bags.
The product must be stored in a cool dry place, away from sunlight, water and sources of heat.

Preparation of the implant site

To obtain a three-dimensional view of the bone available, it is recommended to lift a mucoperiosteal flap. As already mentioned previously, pre-operative clinical and radiographic exams play an important role in determining the position and direction according to which the implants will be positioned. in this stage, a surgical stent will be helpful, acting as a guide during the marking of the cortical bone with the precision drill and in the drilling phase with the 2.00 mm pilot drill.
As a rule a distance of 3.00 mm should be maintained between the perimeter of the implants, and at least 2.00 mm between implants and adjacent natural teeth. The numerous experimental and clinical studies carried out indicate that it is opportune to position the implants more in a lingual or a palatal direction to obtain the best aesthetic results, because this position helps preserve the level of the hard and soft tissues at the crown of the implant.
It is also essential to check that the thickness of the residual bone wall at buccal level is not less than 1.00 mm. The best aesthetic results are obtained with buccal walls of no less than 2.00 mm. If the thickness is smaller, there is a high risk of bone reabsorption failure and exposure of the threads.



The following pages contain information on the drilling sequences for the adequate preparation of all implant types. These procedures come from clinical experience and recommendations taken from numerous studies and clinical protocols for implants of this type. However, it should be remembered that bone types with different densities require different surgical approaches, and the indications below cannot replace the necessary training and knowledge of the doctors, nor their personal experience, which can at times lead to different solutions and indications.
The sequences that follow refer to specific bone types. In expansion techniques or in case of regenerative surgery, or when you want to increase the compaction in poor quality bone, the use of drills can be replaced with the relative osteotomes.
Remember to always use drills with stops correctly inserted. Remember that the drills always prepare a hole that is longer than the implant. For the overpreparation dimensions, refer to page 23 for the pilot drill and page 24 for the final drills. The preparations must be non-traumatic and as gradual as possible, and must be executed quickly and precisely. No overheating of the bone should be generated.
It should also be remembered to initially set the surgical micromotor with the correct torque, reduction and rotation values depending on the operation to be performed.
In particular, **drills** must be used at the speed indicated in each sequence, with the maximum torque and irrigated copiously with cold sterile physiological solution, better if cooled in a refrigerator.

Incorrect insertion of the instruments in the handpiece will cause instrument vibration, eccentric rotation, early wear and shaft buckling. Suitable surgical micromotors only should be used. Micromotors should be checked regularly by their manufacturers, according to the indications given by the same, to prevent potential malfunctions (e.g. axle shifts for transmission shafts, worn or faulty forceps, etc.). Failure to follow the instructions provided may cause surgical problems and damage to the patient's health.

Sweden & Martina distributes **Impla6000** and **Impla7000**, different brushless micromotor for surgical and implant procedures. It perfectly combines reliability, high performances and easy to use procedures. Compact, practical and with a basic design, they come with all the requirements for maximum precision and safety.

Impla6000

Impla7000

Surgical sequence for CSR implants

Surgical sequence for CSR Straight Neck ø 3.00 mm implants

The graphic sequence refers to implants with ø 3.00 mm and H 15.00 mm. The use of the stop is at the dentist's discretion. Their use is recommended, most of all in the case of poor intraoperative visibility. Please remember that the drills over-prepare the length for a measurement reported in the table on page 23 (for pilot and intermediate drills).

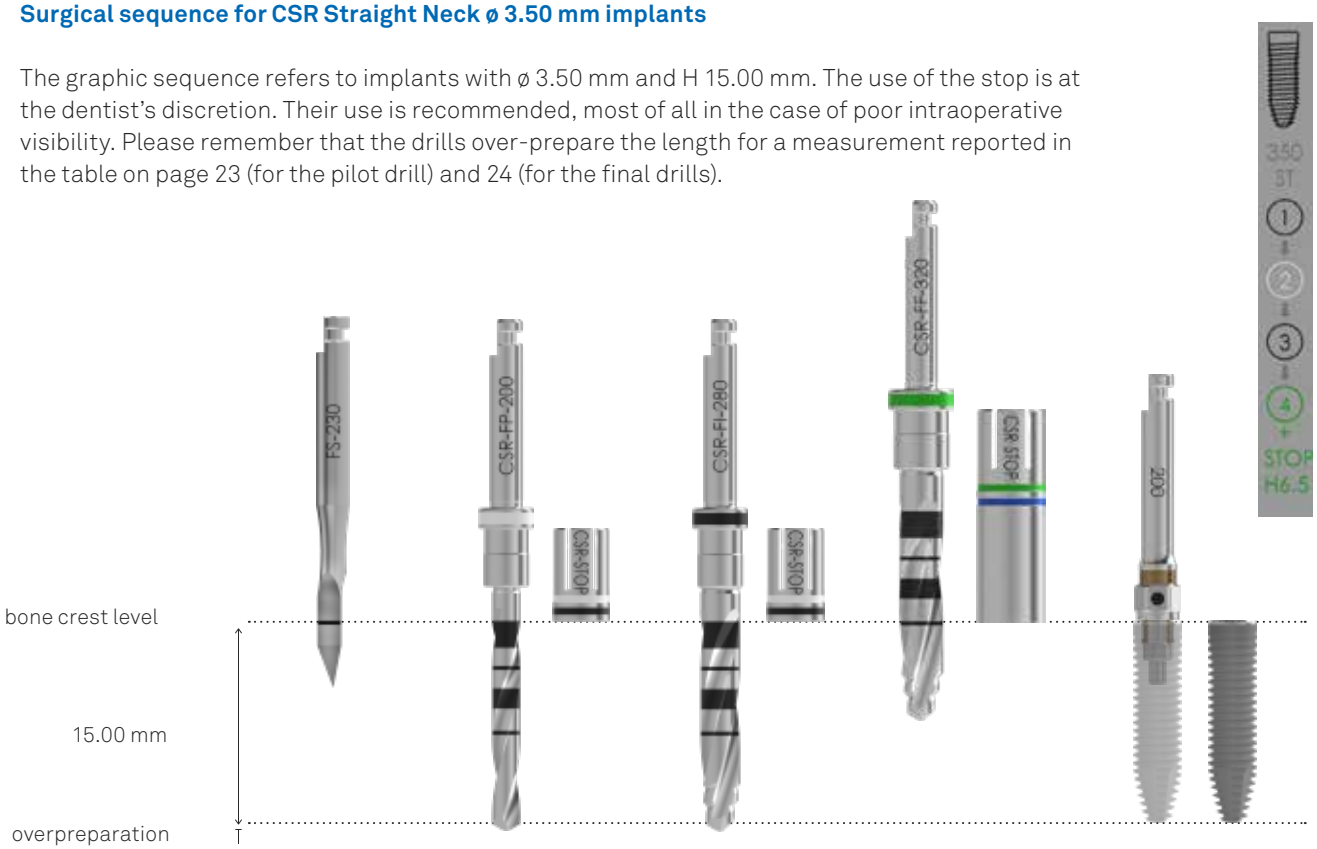
		FS-230	CSR-FP-200	FGS-200/300	EASYC4-EX200-CA
ø 3.00 mm	BONE D1	1,100 rpm	1,100 rpm	1,100 rpm	30 rpm
	BONE D2	1,100 rpm	1,100 rpm	1,100 rpm	30 rpm
	BONE D3	900 rpm	900 rpm	900 rpm	30 rpm
	BONE D4	-	-	-	-

Important warning
Due to the small diameter of the CSR Straight Neck ø 3.00 mm implant, the surgical site is prepared with the pilot and intermediate drill only. The CSR-FP-200 pilot drill has a cylindrical design; it can therefore be used for the preparation of all the heights of the CSR Straight Neck ø 3.00 mm implants up to the relative laser marking.

In the case of surgeries in the distal sectors or in case of poor oral opening of the patient, drills of reduced length are available, to be used without stop. For further details see page 29.

Surgical sequence for CSR Straight Neck ø 3.50 mm implants

The graphic sequence refers to implants with ø 3.50 mm and H 15.00 mm. The use of the stop is at the dentist's discretion. Their use is recommended, most of all in the case of poor intraoperative visibility. Please remember that the drills over-prepare the length for a measurement reported in the table on page 23 (for the pilot drill) and 24 (for the final drills).



		FS-230	CSR-FP-200	CSR-FI-280	CSR-FF-320	EASYC4-EX200-CA
ø 3.50 mm	BONE D1	1,100 rpm	1,100 rpm	1,100 rpm	1,100 rpm	30 rpm
	BONE D2	1,100 rpm	1,100 rpm	1,100 rpm	1,100 rpm	30 rpm
	BONE D3	900 rpm	900 rpm	900 rpm	900 rpm	30 rpm
	BONE D4	900 rpm	900 rpm	osteotome*	osteotome*	30 rpm

Important warning
CSR drills have a cylindrical design; it can therefore be used for the preparation of all the heights of the CSR Straight Neck ø 3.50 mm implants up to the relative laser marking. Regardless of the height of the implant to be inserted, the CSR-FF-320 drill must be used with the H 6.50 mm stop, as shown in the sequence.

Important warning
The insertion of CSR implants with H 6.50 mm must be completed with the micromotor and not with control lever TWL.

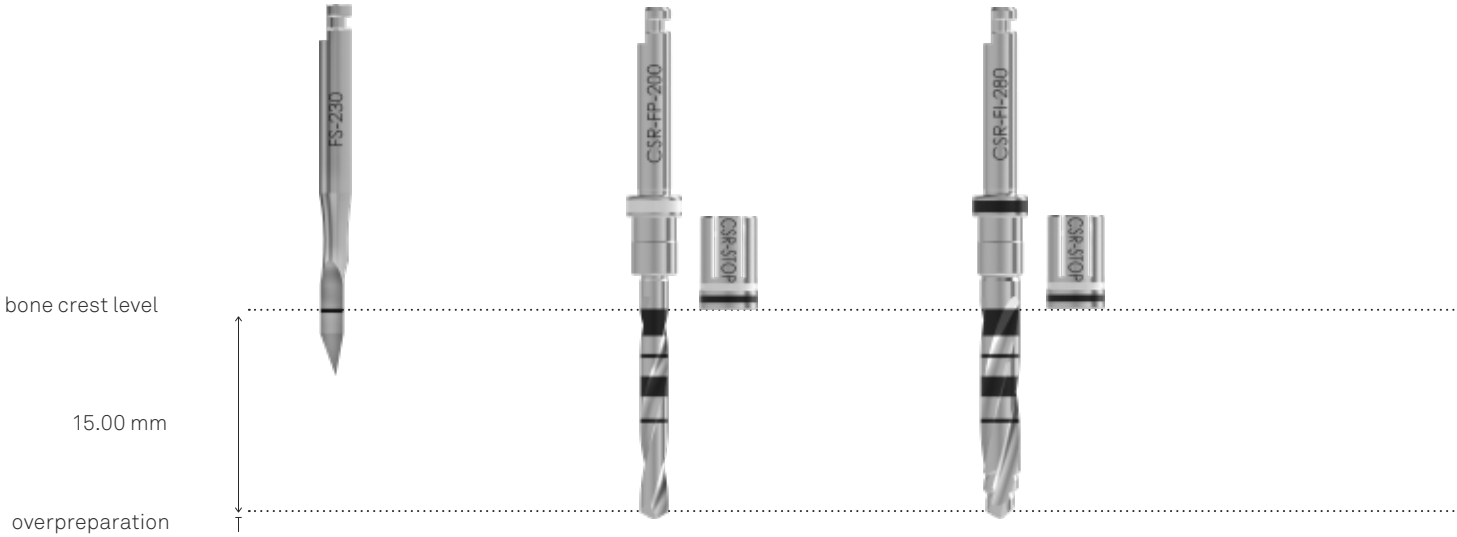
Important note: For implants with H 18.00 mm, preparation must be done without the aid of the stop for the entire length of the working part of the drill (the wider end of the drill serves as a stop and therefore acts as a safety stop).

In the case of surgeries in the distal sectors or in case of poor oral opening of the patient, drills of reduced length are available, to be used without stop. For further details see page 29.

** All the osteotomes have to be used at the reference notch of the implant to be inserted. For more details, please refer to page 28.*

Surgical sequence for CSR Straight Neck ø 3.80 mm implants

The graphic sequence refers to implants with ø 3.80 mm and H 15.00 mm. The use of the stop is at the dentist's discretion. Their use is recommended, most of all in the case of poor intraoperative visibility. Please remember that the drills over-prepare the length for a measurement reported in the table on page 23 (for the pilot drill) and 24 (for the final drills).



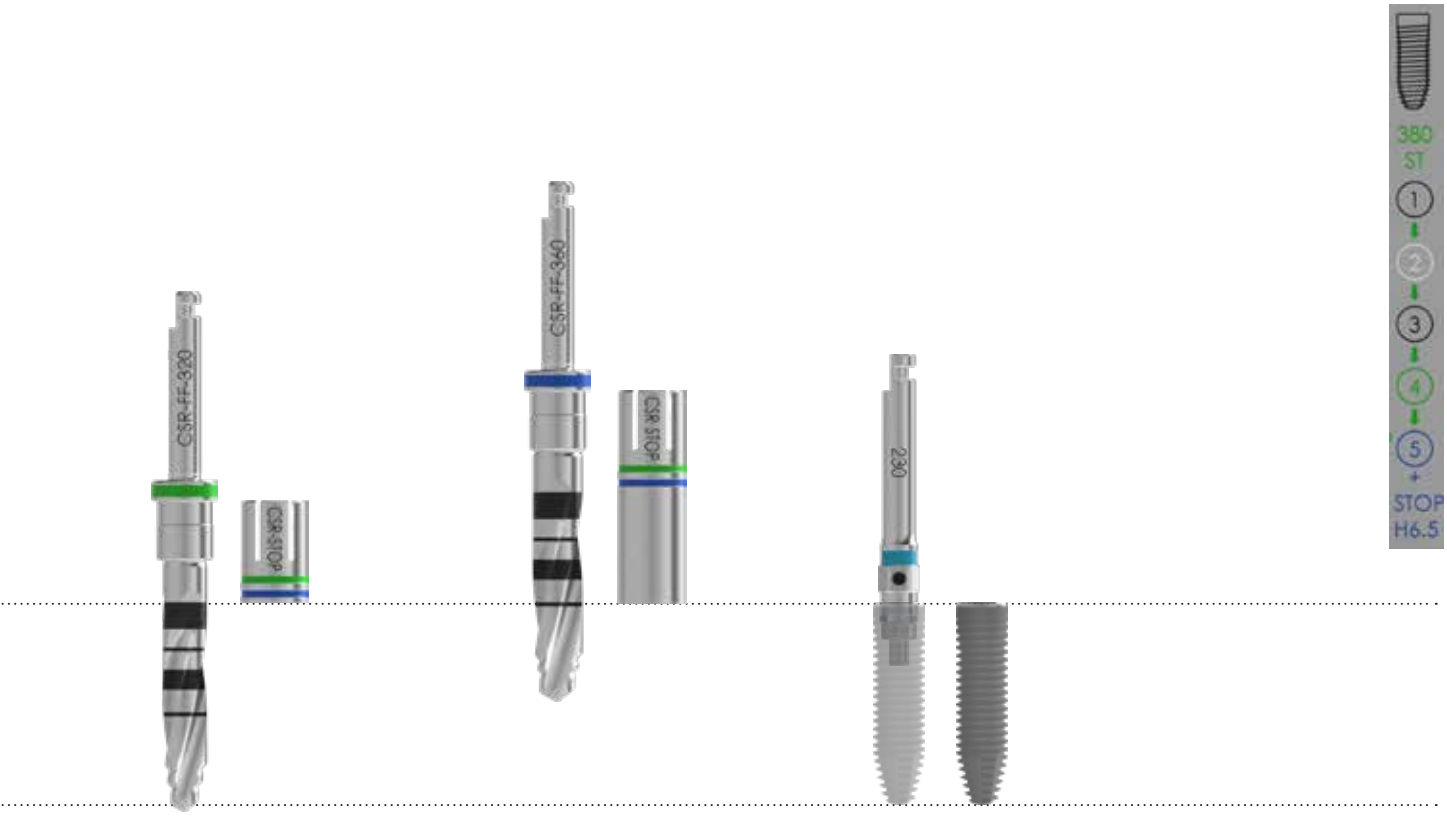
FS-230 **CSR-FP-200** **CSR-FI-280**

ø 3.80 mm	BONE D1	1,100 rpm	1,100 rpm	1,100 rpm
	BONE D2	1,100 rpm	1,100 rpm	1,100 rpm
	BONE D3	900 rpm	900 rpm	900 rpm
	BONE D4	900 rpm	900 rpm	osteotome*

Important warning
CSR drills have a cylindrical design; it can therefore be used for the preparation of all the heights of the CSR Straight Neck ø 3.80 mm implants up to the relative laser marking. Regardless of the height of the implant to be inserted, the CSR-FF-360 drill must be used with the H 6.50 mm stop, as shown in the sequence.

Important warning
The insertion of CSR implants with H 6.50 mm must be completed with the micromotor and not with control lever TWL.

In the case of surgeries in the distal sectors or in case of poor oral opening of the patient, drills of reduced length are available, to be used without stop. For further details see page 29.



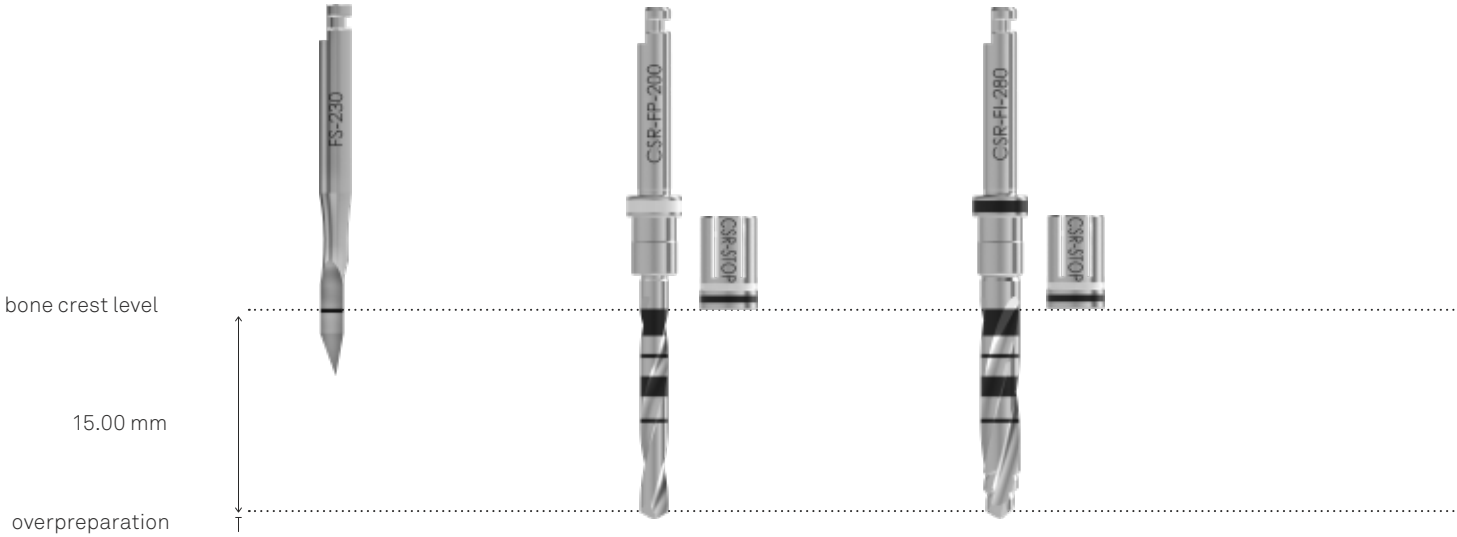
CSR-FF-320	CSR-FF-360	EASYC4-EX230-CA
1,100 rpm	1,100 rpm	30 rpm
1,100 rpm	1,100 rpm	30 rpm
900 rpm	-	30 rpm
osteotome*	-	30 rpm

***Important note**: For implants with H 18.00 mm, preparation must be done without the aid of the stop for the entire length of the working part of the drill (the wider end of the drill serves as a stop and therefore acts as a safety stop).*

** All the osteotomes have to be used at the reference notch of the implant to be inserted. For more details, please refer to page 28.*

Surgical sequence for CSR Wide Neck ø 3.80 mm implants

The graphic sequence refers to implants with ø 3.80 mm and H 15.00 mm. The use of the stop is at the dentist's discretion. Their use is recommended, most of all in the case of poor intraoperative visibility. Please remember that the drills over-prepare the length for a measurement reported in the table on page 23 (for the pilot drill) and 24 (for the final drills).



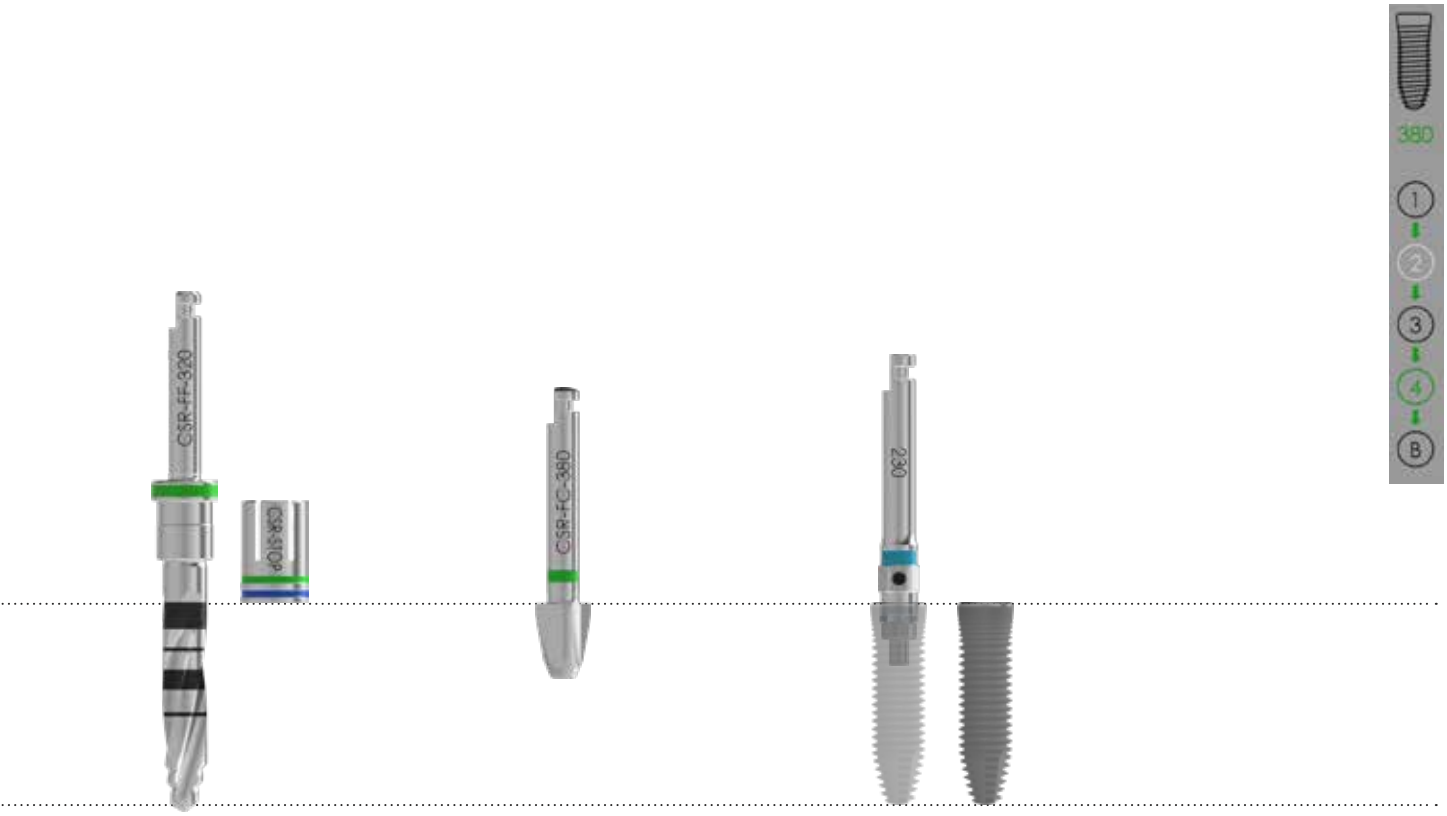
FS-230 **CSR-FP-200** **CSR-FI-280**

ø 3.80 mm	BONE D1	1,100 rpm	1,100 rpm	1,100 rpm
	BONE D2	1,100 rpm	1,100 rpm	1,100 rpm
	BONE D3	900 rpm	900 rpm	900 rpm
	BONE D4	900 rpm	900 rpm	osteotome*

Important warning
CSR drills have a cylindrical design; it can therefore be used for the preparation of all the heights of the CSR Wide Neck ø 3.80 mm implants up to the relative laser marking.

Important warning
The insertion of CSR implants with H 6.50 mm must be completed with the micromotor and not with control lever TWL.

In the case of surgeries in the distal sectors or in case of poor oral opening of the patient, drills of reduced length are available, to be used without stop. For further details see page 29.



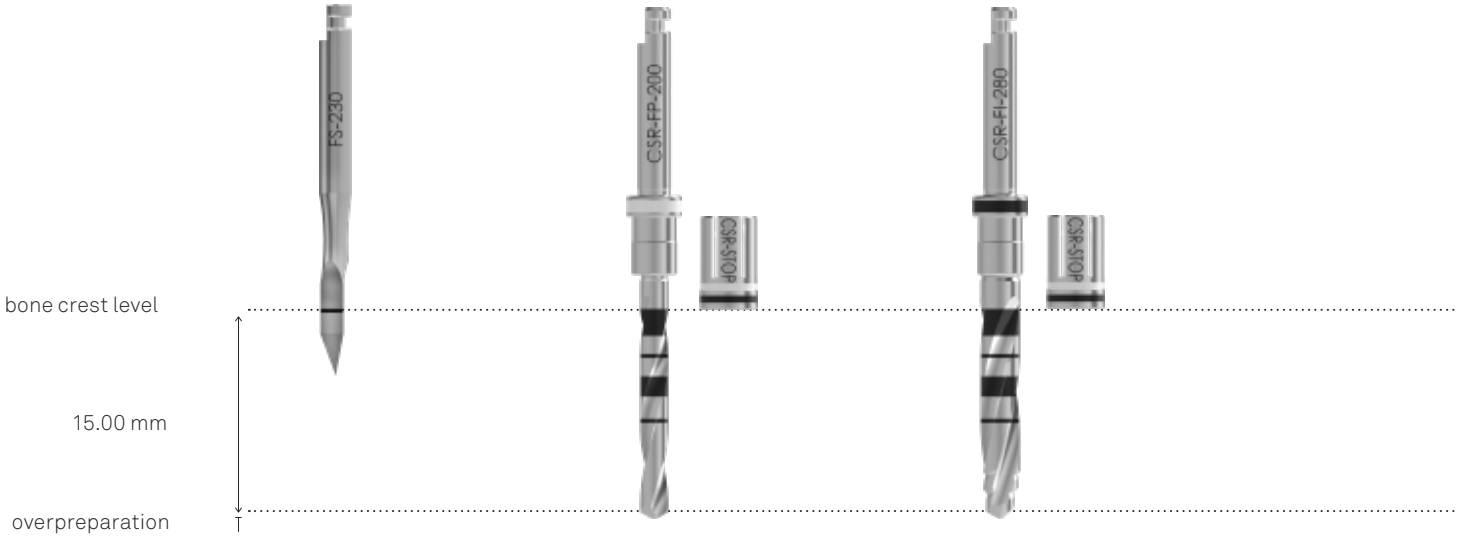
CSR-FF-320	CSR-FC-380	EASYC4-EX230-CA
1,100 rpm	1,100 rpm	30 rpm
1,100 rpm	1,100 rpm	30 rpm
900 rpm	-	30 rpm
osteotome*	-	30 rpm

***Important note**: For implants with H 18.00 mm, preparation must be done without the aid of the stop for the entire length of the working part of the drill (the wider end of the drill serves as a stop and therefore acts as a safety stop).*

** All the osteotomes have to be used at the reference notch of the implant to be inserted. For more details, please refer to page 28.*

Surgical sequence for CSR Wide Neck ø 4.20 mm implants

The graphic sequence refers to implants with ø 4.20 mm and H 15.00 mm. The use of the stop is at the dentist's discretion. Their use is recommended, most of all in the case of poor intraoperative visibility. Please remember that the drills over-prepare the length for a measurement reported in the table on page 23 (for the pilot drill) and 24 (for the final drills).



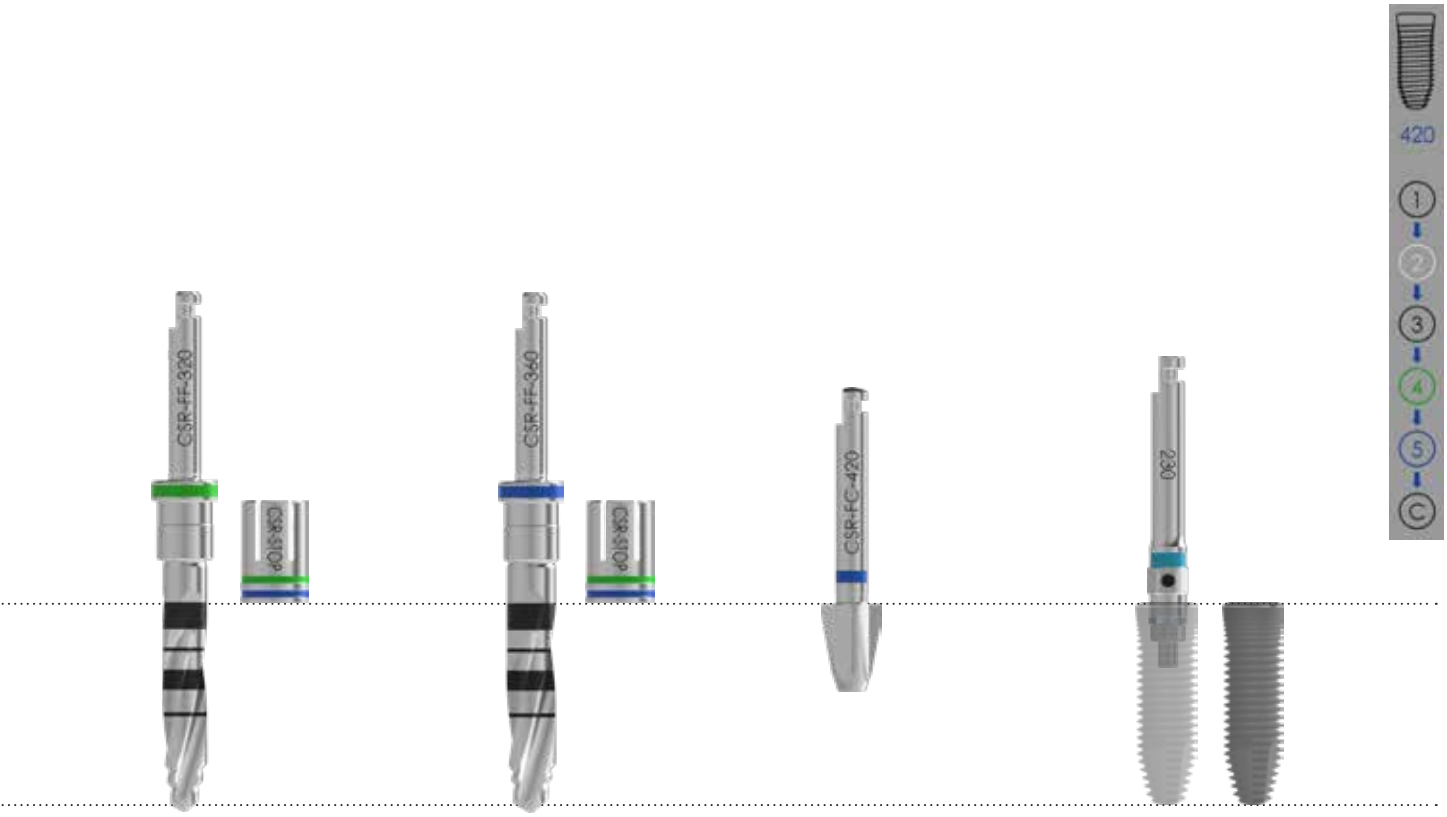
FS-230 **CSR-FP-200** **CSR-FI-280**

ø 4.20 mm	BONE D1	1,100 rpm	1,100 rpm	1,100 rpm
	BONE D2	1,100 rpm	1,100 rpm	1,100 rpm
	BONE D3	900 rpm	900 rpm	900 rpm
	BONE D4	900 rpm	900 rpm	osteotome*

Important warning
CSR drills have a cylindrical design; it can therefore be used for the preparation of all the heights of the CSR Wide Neck ø 4.20 mm implants up to the relative laser marking.

Important warning
The insertion of CSR implants with H 6.50 mm must be completed with the micromotor and not with control lever TWL.

In the case of surgeries in the distal sectors or in case of poor oral opening of the patient, drills of reduced length are available, to be used without stop. For further details see page 29.



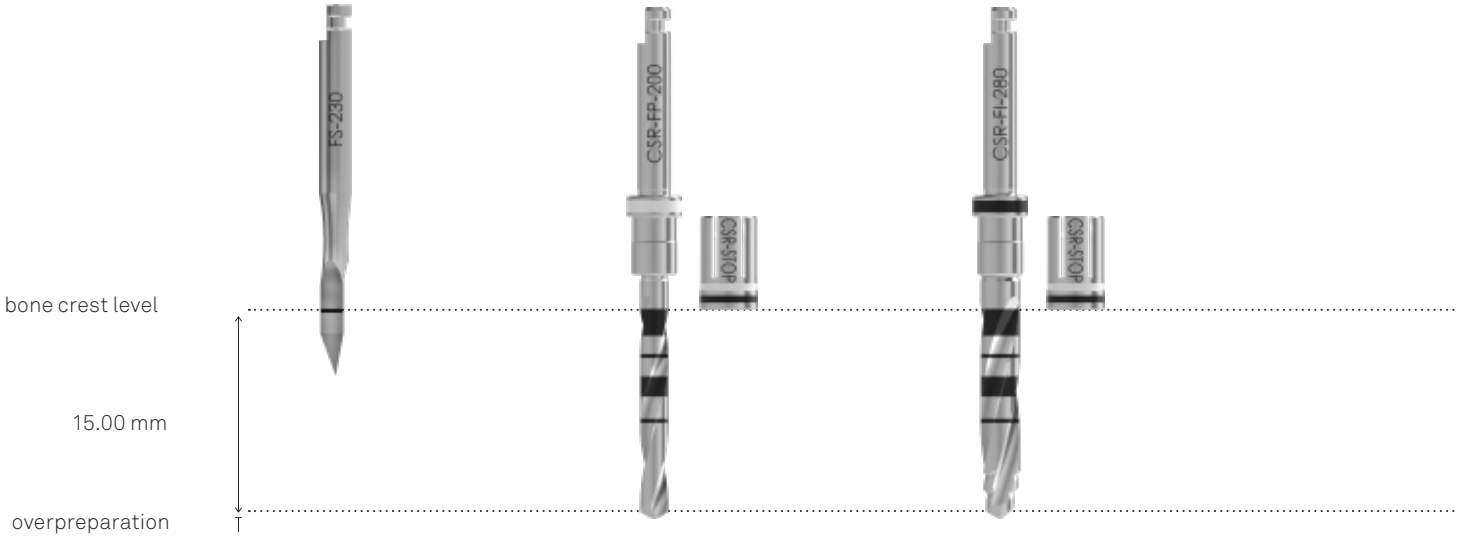
CSR-FF-320	CSR-FF-360	CSR-FC-420	EASYC4-EX230-CA
1,100 rpm	900 rpm	1,100 rpm	30 rpm
1,100 rpm	900 rpm	1,100 rpm	30 rpm
900 rpm	900 rpm	-	30 rpm
osteotome*	osteotome*	-	30 rpm

***Important note**: For implants with H 18.00 mm, preparation must be done without the aid of the stop for the entire length of the working part of the drill (the wider end of the drill serves as a stop and therefore acts as a safety stop).*

** All the osteotomes have to be used at the reference notch of the implant to be inserted. For more details, please refer to page 28.*

Surgical sequence for CSR Reduced Neck ø 4.20 mm implants

The graphic sequence refers to implants with ø 4.20 mm and H 15.00 mm. The use of the stop is at the dentist's discretion. Their use is recommended, most of all in the case of poor intraoperative visibility. Please remember that the drills over-prepare the length for a measurement reported in the table on page 23 (for the pilot drill) and 24 (for the final drills).



		FS-230	CSR-FP-200	CSR-FI-280
ø 4.20 mm	BONE D1	1,100 rpm	1,100 rpm	1,100 rpm
	BONE D2	1,100 rpm	1,100 rpm	1,100 rpm
	BONE D3	900 rpm	900 rpm	900 rpm
	BONE D4	900 rpm	900 rpm	osteotome*

Important warning
CSR drills have a cylindrical design; it can therefore be used for the preparation of all the heights of the CSR Reduced Neck ø 4.20 mm implants up to the relative laser marking.

Important warning
The insertion of CSR implants with H 6.50 mm must be completed with the micromotor and not with control lever TWL.

In the case of surgeries in the distal sectors or in case of poor oral opening of the patient, drills of reduced length are available, to be used without stop. For further details see page 29.

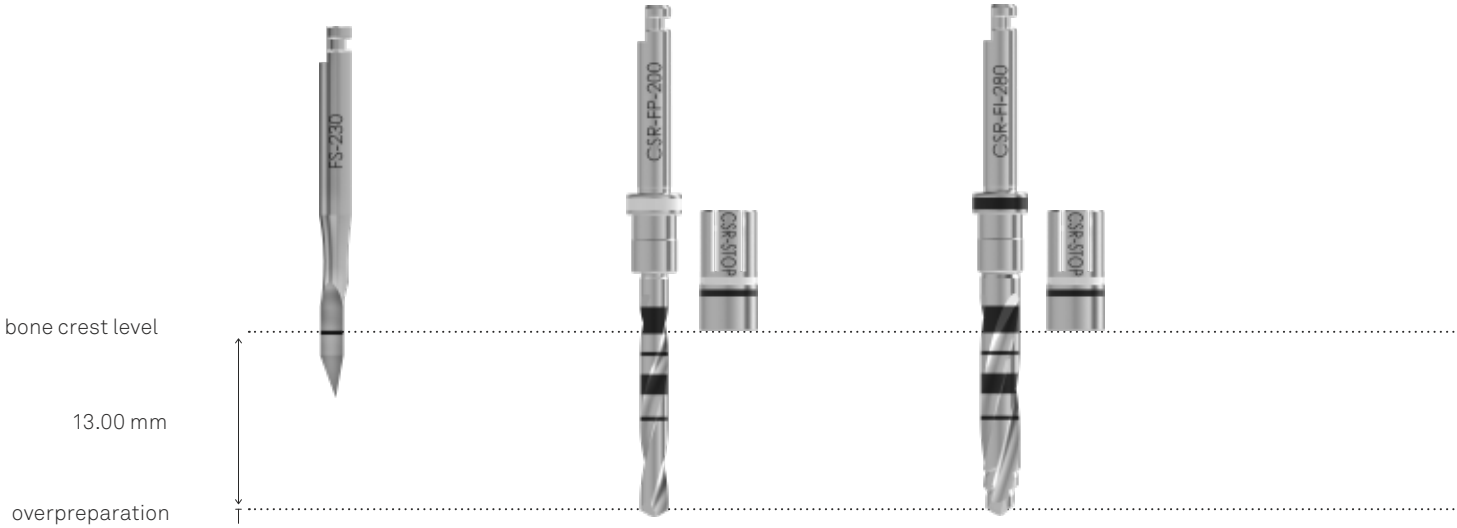
CSR-FF-320	CSR-FF-360	EASYC4-EX230-CA
1,100 rpm	900 rpm	30 rpm
1,100 rpm	900 rpm	30 rpm
900 rpm	900 rpm	30 rpm
osteotome*	osteotome*	30 rpm

***Important note**: for implants with H 18.00 mm, preparation must be done without the aid of the stop for the entire length of the working part of the drill (the wider end of the drill serves as a stop and therefore acts as a safety stop).*

** All the osteotomes have to be used at the reference notch of the implant to be inserted. For more details, please refer to page 28.*

Surgical sequence for CSR Reduced Neck ø 5.00 mm implants

The graphic sequence refers to implants with ø 5.00 mm and H 13.00 mm. The use of the stop is at the dentist's discretion. Their use is recommended, most of all in the case of poor intraoperative visibility. Please remember that the drills over-prepare the length for a measurement reported in the table on page 23 (for the pilot drill) and 24 (for the final drills).

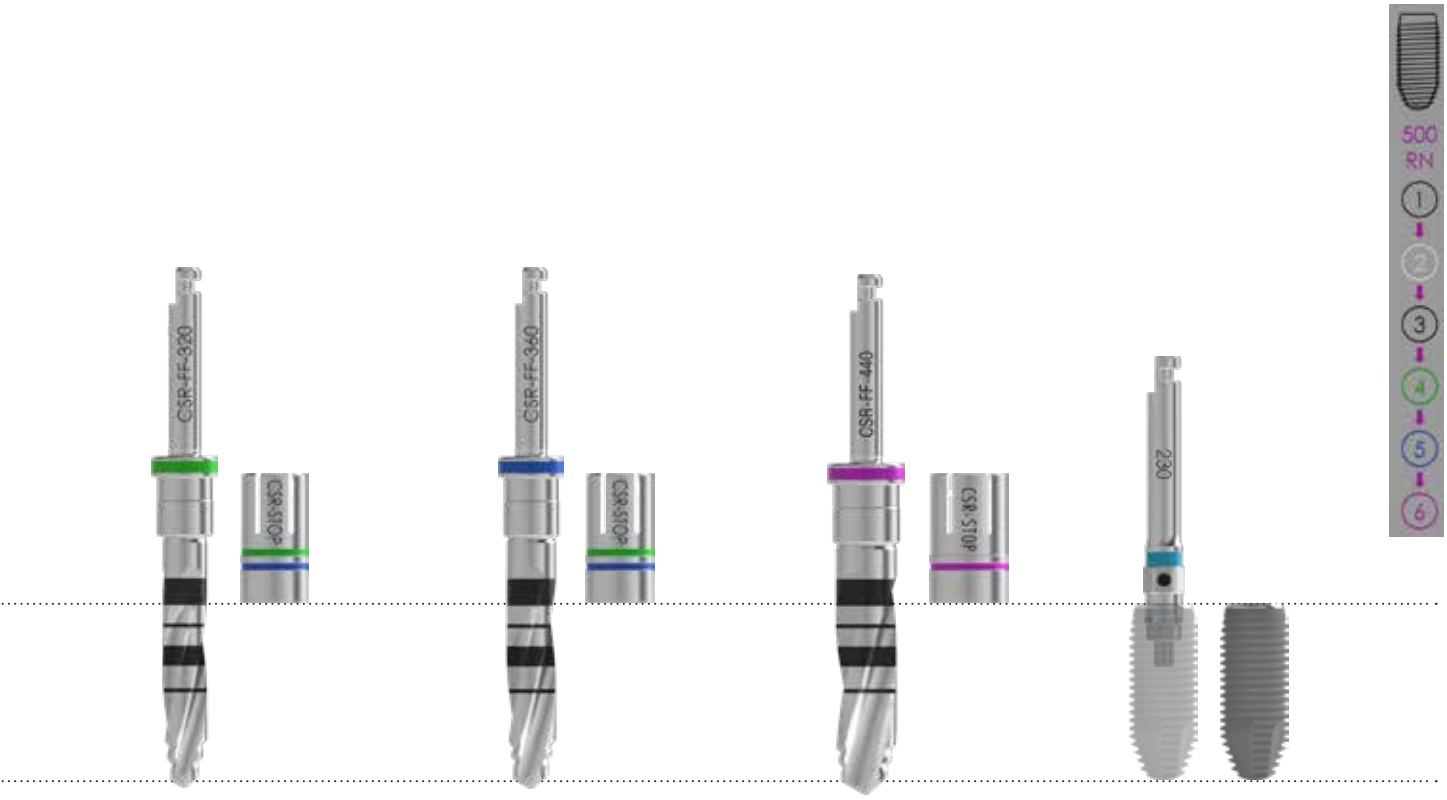


		FS-230	CSR-FP-200	CSR-FI-280
ø 5.00 mm	BONE D1	1,100 rpm	1,100 rpm	1,100 rpm
	BONE D2	1,100 rpm	1,100 rpm	1,100 rpm
	BONE D3	900 rpm	900 rpm	900 rpm
	BONE D4	900 rpm	900 rpm	osteotome*

Important warning
CSR drills have a cylindrical design; it can therefore be used for the preparation of all the heights of the CSR Reduced Neck ø 5.00 mm implants up to the relative laser marking.

Important warning
The insertion of CSR implants with H 6.50 mm must be completed with the micromotor and not with control lever TWL.

In the case of surgeries in the distal sectors or in case of poor oral opening of the patient, drills of reduced length are available, to be used without stop. For further details see page 29.



CSR-FF-320	CSR-FF-360	CSR-FF-440	EASYC4-EX230-CA
1,100 rpm	1,100 rpm	900 rpm	30 rpm
1,100 rpm	1,100 rpm	900 rpm	30 rpm
900 rpm	900 rpm	900 rpm	30 rpm
osteotome*	osteotome*	osteotome*	30 rpm

** All the osteotomes have to be used at the reference notch of the implant to be inserted. For more details, please refer to page 28.*

Implant insertion

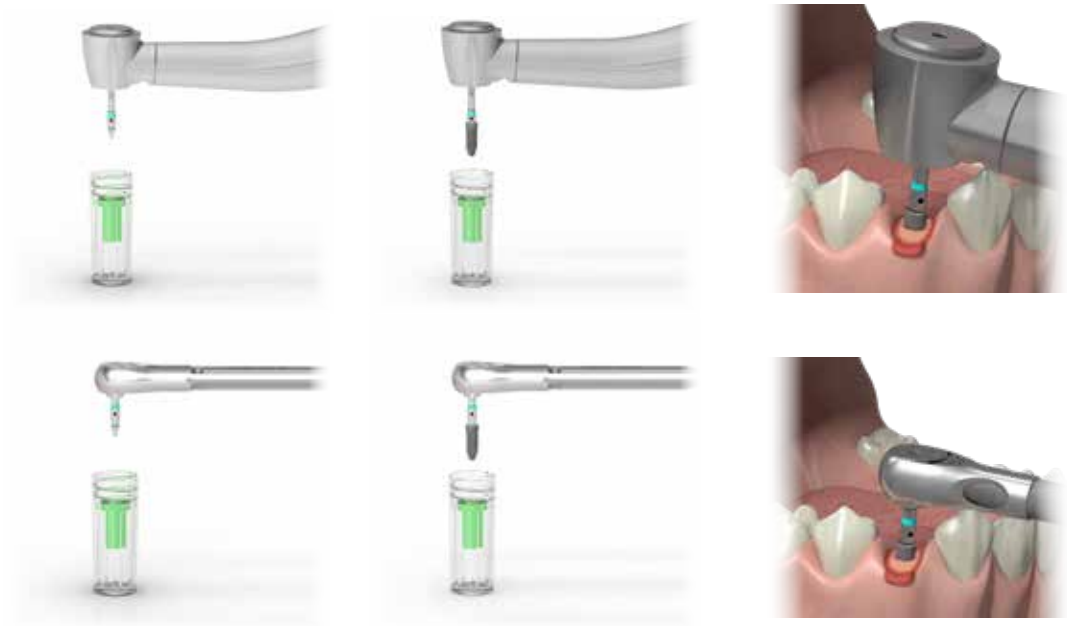
1 Use the patient label inside the pack for the patient's medical file, and apply it to the Dental Card: this will make it easier to record the patient's treatment plan and will keep a trace of the batch used.

2 Open the blister pack and place the vial inside it on a sterile surface (e.g. on a disposable towel or a sterile cloth) next to the operating area.

3 Immediately before the insertion into the oral cavity, remove the blue cap of the vial, making sure not to remove the transparent cap containing the surgical cover screw. The implant holding cylinder inside the vial and the surgical cover screw are coloured according to a colour code that allows the rapid identification of the implant diameter.

Standard procedure

When the vial is opened, the mounter is exposed with the hexagon ready to be engaged. The implant may be picked up using the dedicated Easy Insert driver and then screwed mechanically in place with the aid of a suitable surgical micromotor with torque control set at a screwing speed of 20 rpm and max torque 70 Ncm.
The driver has been tested up to 70 Ncm and has not presented any deformations or failures. Instruments with torque control, both mechanical and normal, are regularly calibrated with a suitable calibrated instrument.



After implant insertion

Healing times
It is essential to respect the healing times recommended in implant surgery, and periodically checking the progress of osseointegration with X-rays. The preliminary healing times of an implant are influenced by the quality of the receiving bone. In the case of immediate load, consider the warnings reported on pages 4-7.
In the case of a deferred loading, in order to minimize the discomfort conditioned by the biological times for the osseointegration, the use of mobile temporary prosthesis has to be carried out with prudence, widely unloading the prosthesis.

After healing is completed, the surgical cover screws are removed from the implants. If the right angle driver is used, the surgical micromotor must be set with the following parameters: 20 rpm and torque 10 Ncm. After that, depending on the protocol adopted, proceed with the adaptation of the profiles of the tissues with a proper temporary or with proper healing abutments. It is recommended to secure the healing abutments manually or at any rate with a torque no greater than 10 Ncm.

Intraoperative removal of implants if necessary

If a previously inserted implant needs to be removed, this can be done by directly engaging the hexagonal driver connection of the implant.
Accurately clean away blood and any other residues produced during insertion from the implant socket by irrigating the site.

Insert the hexagon of the driver inside the implant connection, being very careful that the instrument is on-axis with the implant and that it completely and closely engages the internal hexagon. Use the driver BC-EX230 or BL-EX230 for CSR implants with DAT connection or BC-EX200 or BL-EX200 for CSR implants with DAT-N connection. Drivers not included in the surgical kit.

Block the head of the CRI5-KIT ratchet or of the TWL key and connect it with the hexagonal tip of the driver making sure that the laser-etched arrow on the ratchet head indicates an anticlockwise direction, and move it in this direction while keeping the driver/ratchet assembly on-axis with the index finger.
It is recommended to apply a higher torque than the one applied during the insertion phase.
Once it has been unscrewed pick up the removed implant using sterile forceps.

Maintenance of the prosthesis

Some implant restoration-related complications are reported in the literature. These complications may lead to a loss of osseointegration and implant failure. Correct maintenance by the patient, satisfactory home dental hygiene and regular sessions with a professional hygienist increase the device service life. Complications such as the unscrewing of the screws securing the prostheses to implants or bone reabsorption causing the loss of the gingival support surface in the case of removable prostheses can be easily prevented with regular check-ups. If post or prostheses screws need to be tightened, this must be done by the practitioner, using suitable instruments with control over tightening torque.

The calibration of these instrument should be checked regularly. In the event of complications of this kind, patients should contact their practitioner as soon as possible, so that the necessary work to restore correct orthodontic functionality can be carried out. Delays in consulting the practitioner may lead firstly to the fracture of the connection screw or of the prosthesis, and secondly to the loss of the implant, thereby compromising rehabilitation results. Practitioners must make this clear to their patients. Complications may be biological (impaired integration) or mechanical (fracture of a component due to excessive loads). If there are no complications, duration depends on the devices and the whole restoration system depends on mechanical resistance in relation to the fatigue accumulated by the device.

Responsibility for defective products and warranty terms

Optimal patient care and attention to their needs are necessary conditions for the success of implantation procedures and, therefore, patients must be carefully selected and informed of the associated risks and obligations connected with the treatment and encouraged to cooperate with the dentist in the interests of the success of the same treatment. The patient must, therefore, maintain good hygiene, which should be confirmed during check-up appointments, guaranteed and recorded and the practitioners instructions and orders shall be observed. The warranty only covers manufacturing defects as long as the faulty piece is identified by the article code and batch number and returned within the validity period of the warranty. The warranty terms are available on the website www.sweden-martina.com.

Disposal

If removed from the oral cavity due to biological or mechanical failure, the implant fixtures must be disposed of as biological waste. The surgical instruments are made of small components, mostly metal. They may therefore be disposed of as metal wastes. If dirty, they must be disposed of as biological wastes. In general, the local regulations apply.

Composition of the materials

The materials used for manufacturing the surgical instruments illustrated in this manual were selected based on the properties indicated for their intended use according to directive 93/42, implemented in Italy with Law 46/97, Annex I – Essential Requirements, point 7.1.

Implants
Implants are made of Gr. 4 commercially pure titanium, in compliance with harmonized standards. Although very rare, titanium allergy is possible. Patients should therefore always be asked whether they have allergies of this type.
The characteristics of the Gr. 4 titanium used are listed below.

Grade 4 titanium (Cold worked)* ASTM F67-13, ISO 5832-2:2012

chemical composition	maximum allowed values (%)	tolerance
nitrogen	0.05	+/- 0.02
carbon	0.10	+/- 0.02
hydrogen	0.015	+/- 0.002
iron	0.25	+/- 0.10 (%<0.25) +/- 0.15 (%>0.25)
oxygen	0.20	+/- 0.02 (%<0.20) +/- 0.03 (%>0.20)
titanium	a bilancio	-

** This technical information complies with the express specifications of the regulations in force on the use of Gr. 4 titanium in implantology:*
- *ASTM F67-13: Standard Specification for unalloyed titanium, for surgical implant applications.*
- *ISO 5832-2: 2012: Implants for surgery – Metallic materials – Part 2: Unalloyed titanium.*

***Important note**: the use of cold worked Gr. 4 titanium bars for the production of Sweden & Martina implants allows the exploitation of mechanical characteristics higher than those required by applicable standards. Furthermore, the excellent results documented during 20 years of clinical experience corroborate the choice of the coldworking production process and of ZirTi surface treatments, which express and enhance the raw material potential selected by Sweden & Martina.*

Surgical instrumentation
Depending on the type of component, surgical instruments are made of:
- Gr. 5 titanium
- 1.4197 steel
- 1.4542 steel
- 1.4305 (AISI 630) steel
- 1.4108 (AISI 303) steel
- 1.4108 steel
- 1.4112 steel

Patients must be asked if they are allergic to any of the materials used.

Identification of the manufacturer

The manufacturer of the CSR implants and the relative surgical instruments is:

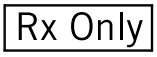
Sweden & Martina
Via Veneto 10 - 35020 Due Carrare (Padua) - Italy
Tel. +39 049.9124300 - Fax + 39 049.9124290
e-mail: info@sweden-martina.com
www.sweden-martina.com

In accordance with Directive 93/42/EEC implemented in Italy with L.D. 46/97 of 26/03/97, Annex IX, Sweden & Martina identifies the risk class of these products as indicated in Table 01.
Even though they can be used with all patients who have suitable therapeutic indications, dental implants and the respective surgical instruments must be used only by professional dentists or surgeons with the necessary qualifications and training.

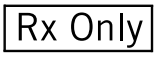
Table 01 - Risk classes

device	directive 93/42	packing	rule Annex IX	risk class
Implant fixtures for dental use, belonging to the CSR implant system	Implantable devices intended for long-term use (over 30 days)	Single-use sterile pack, fixture complete with surgical cover screw	8	IIb
Surgical cover screws	Implantable devices intended for long-term use (over 30 days)	Sold in packs complete with the respective fixtures or sold individually (single-use sterile pack)	8	IIb
Complete surgical kits	Reusable surgical instruments	Sold in NON sterile packages	6	IIa
Radel instrument tray and X-ray templates	Non invasive medical devices	Sold in NON-STERILE packs	1	I
Surgical drills (precision, final, for distal use); extension for drills; stops for drills; drivers and screwdrivers intended for use with a micromotor	Re-usable invasive surgical instruments for temporary use (for less than 60 minutes at a time)	Sold in NON-STERILE packs	6	IIa
Osteotomes/bone expanders; screwdrivers, drivers and digital drivers, hex drivers, manual knobs, depth gauges, parallelism pins	Re-usable invasive surgical instruments for temporary use (for less than 60 minutes at a time), not intended to be connected to an active medical device	Sold in NON-STERILE packs	6	I

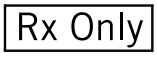
Key to symbols used on the implant packs:

description	symbol
Caution! See instructions for use	
Batch number	
Code	
Manufacturer	
Consult instructions for use	
CE conformity mark for class IIa and IIb products	
American federal law restricts this device to sale by or by order of a professional practitioner	
Do not resterilize	
Single use product, do not reuse	
Do not use if the packaging is damaged	
Sterile device, sterilization by radiation	
Expiry date	

Key to symbols used on surgical instrument packs:

description	symbol
Caution! See instructions for use	
Batch number	
Code	
Manufacturer	
Consult instructions for use	
CE conformity mark for class IIa and IIb products	
CE conformity mark for class I products	
American federal law restricts this device to sale by or by order of a professional practitioner	
NON-STERILE device	

Key to symbols used on prosthetic component packs:

description	symbol
Caution! See instructions for use	
Batch number	
Code	
Manufacturer	
Consult instructions for use	
CE conformity mark for class IIa and IIb products	
CE conformity mark for class I products	
American federal law restricts this device to sale by or by order of a professional practitioner	
Single use product, do not reuse	
NON-STERILE device	

THIS MANUAL'S LAST REVISION DATE IS OCTOBER 2018.

The medical devices contained in this manual have been designed and manufactured in accordance with the most recent directives and harmonized standards applicable to the materials used, the production processes, the sterilization, the information supplied and the packaging.

MC-IMP-CSR-E

rev.10-18

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The implants, standard prosthetic components and surgical instruments contained in this catalogue are Medical devices and are manufactured by Sweden & Martina S.p.A. They conform to the ISO 9001 and ISO 13485 standards and are certified with the CE Mark (Class I) and CE 0476 mark (Class IIA and class IIB) in compliance with Regulation (EU) Medical Devices n. 2017/745.

We have met the good manufacturing standards (GMP) set forth by many countries worldwide, including the United States FDA.