



GLOBALWIN

IMPLANT SYSTEM

GLOBALWIN and GLOBALWIN SLIM operating protocols



BIOSAFIN

Partner of



Making Your Life Better.

BIOSAFIN

Partner of



Making Your Life Better.

Specialised Company

BIOSAFIN specialises in the manufacture and sale of devices and instruments for implantology and oral surgery. Research and Development is at the heart of our business, and we aim to achieve high product performance through the development of innovative scientific and technological content, while constantly improving Quality.

Scientifically and clinically tested product quality

The certified quality of our products – which all undergo strict production checks – and the solutions we provide, which are always current and in line with patient needs, provide dental surgeons with maximum peace of mind.

The solid scientific background in which the devices are developed, allows for combining technological innovation and compatibility, thus avoiding demanding changes in operative procedures or costly replacements of materials for the dental surgery Team.

Company certifications

BIOSAFIN is a company certified to:

ISO 9001 standard, which certifies the entire work process, from start to finish, further demonstrating compliance with quality standards considered optimal for the protection of product Users – Professionals – and the end user – the Patient.

ISO 13485 specifically relevant to the quality of Medical Devices.

The quality standards required for Certification are periodically examined and reviewed.



TRADEMARKS

- GLOBALWIN®
- MRS Micro Rough Surface®

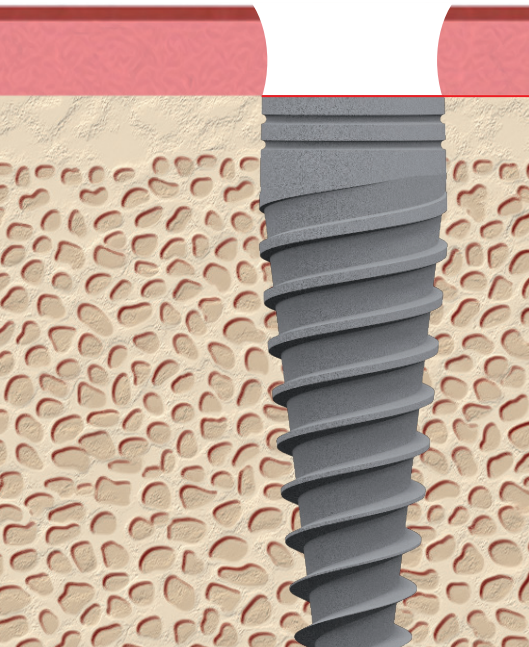
PATENTS REGISTERED

- Trumpet abutment: patent no. EP 3424460
- CAB - Clip Abutment Bar:
 - European Patent n. 114 250327
 - International Patent PCT/EP2011/072448

GLOBALWIN Implants

Universal LINE

Each implant is equipped with a
Cover screw



Implant diameter



Implant cover screw included

CSC40

Implant length

CODE

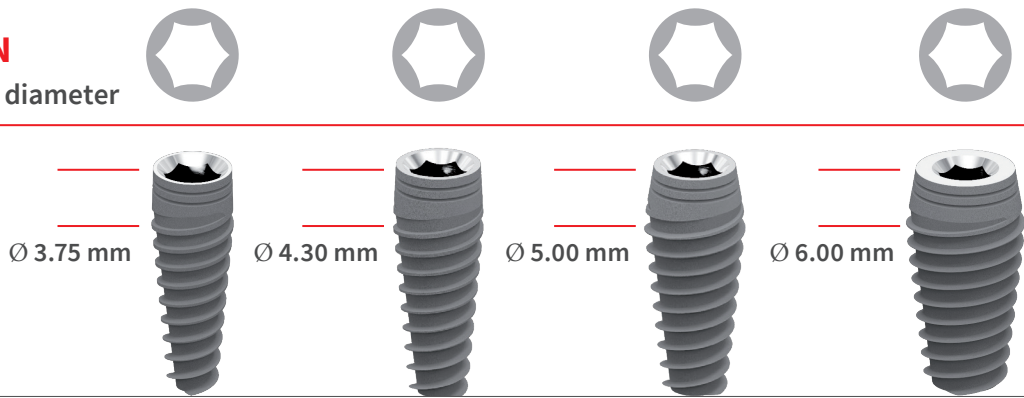
6 mm	-
8 mm	GU375008MRS
10 mm	GU375010MRS
11.5 mm	GU375115MRS
13 mm	GU375013MRS
15 mm	GU375015MRS
18 mm	GU375018MRS

One single CONNECTION

Same shape and diameter

Differentiated platform

Implant



CSC40

CODE



CSC40

CODE



CSC60

CODE

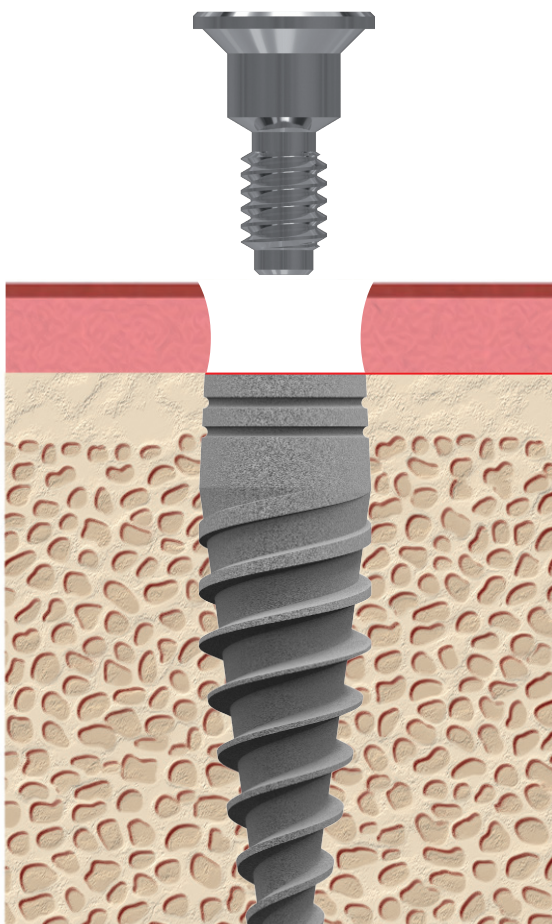
- GU430006MRS
- GU430008MRS
- GU430010MRS
- GU430115MRS
- GU430013MRS
- GU430015MRS
- GU430018MRS

- GU500006MRS
- GU500008MRS
- GU500010MRS
- GU500115MRS
- GU500013MRS
- GU500015MRS

- GU600006MRS
- GU600008MRS
- GU600010MRS
- GU600115MRS
- GU600013MRS
-
-

GLOBALWIN SLIM IMPLANTS

Each implant is equipped with a
Cover screw

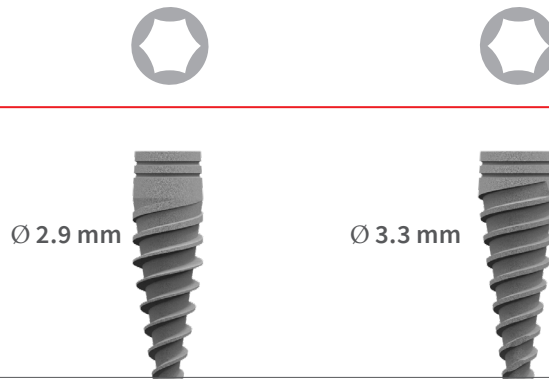


One single CONNECTION

Same shape and diameter

Differentiated platform

Implant



Implant diameter



Implant cover screw included

VT29SI

VT33SI

Implant length

CODE

CODE

10 mm

29010GSI

33010GSI

11.5 mm

29115GSI

33115GSI

13 mm

29013GSI

33013GSI

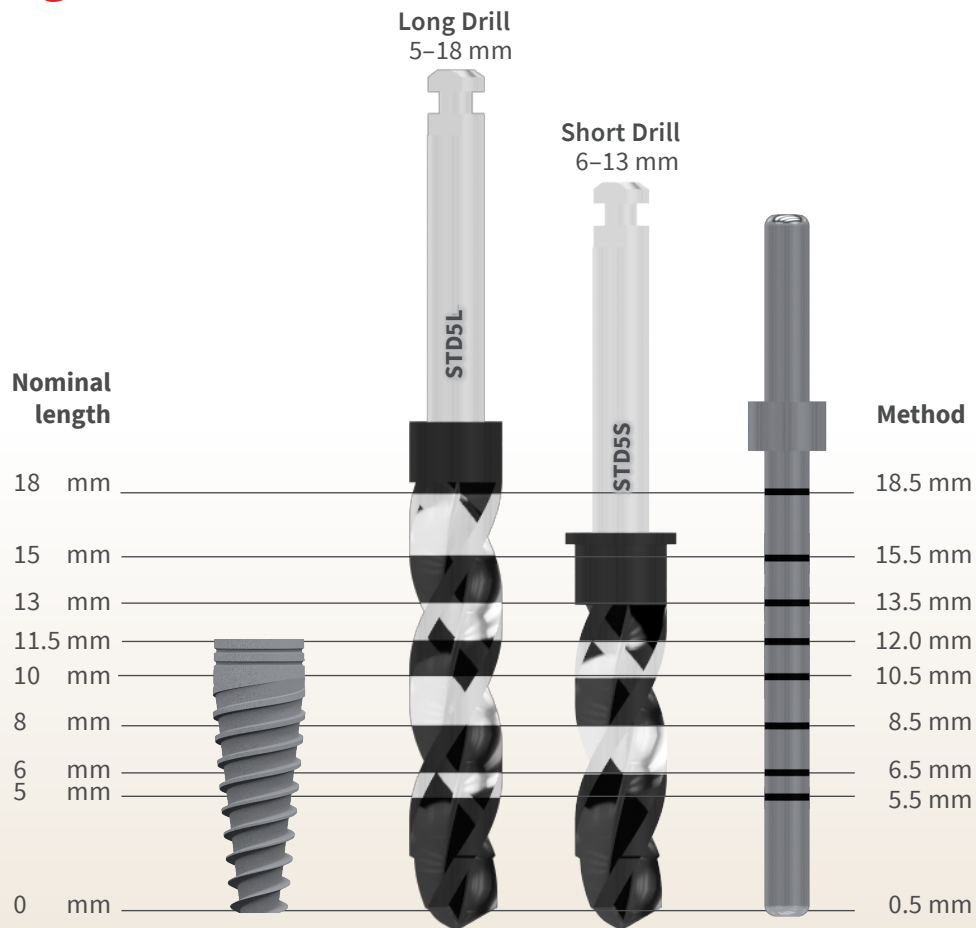
15 mm

29015GSI

33015GSI

Drilling Stage

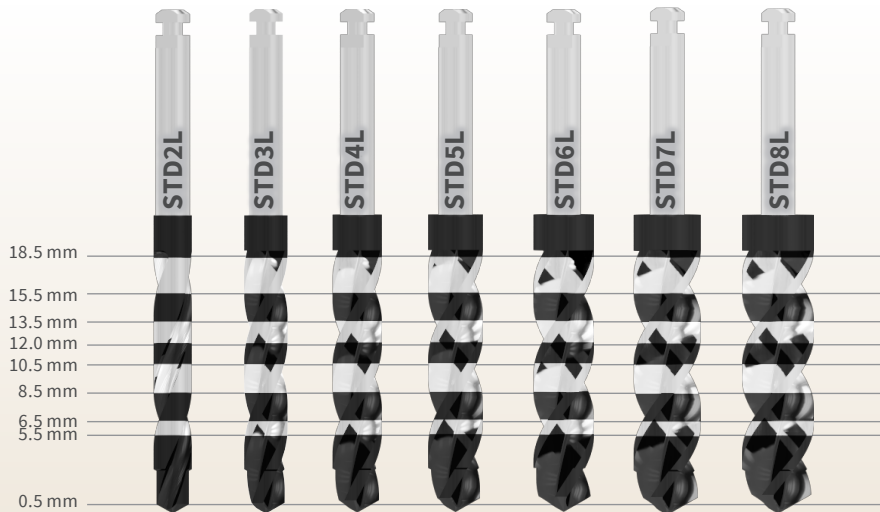
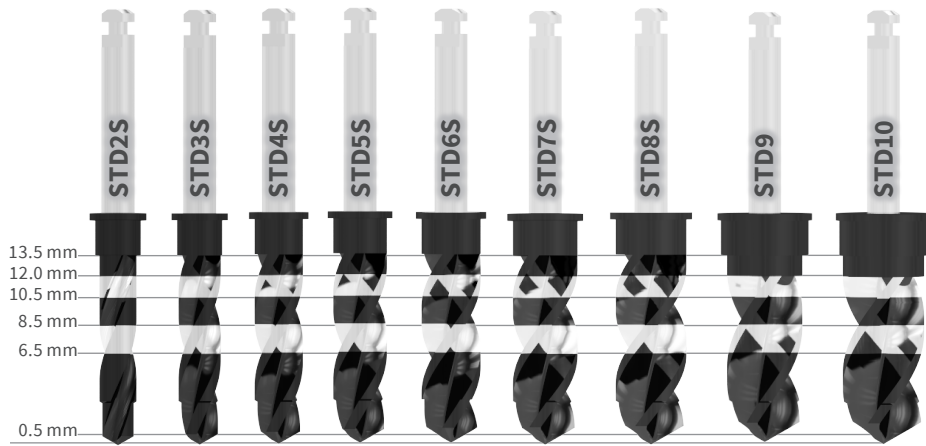
Relationship between Drills and lengths of the Implants



The drill lengths are overestimated by 0.5 mm compared to the endosseous length of the implants.

Recommendations:

- For reasons of safety, it is advisable to replace the drills after a maximum of 50 cuts.
- In any case, check the cutting efficiency before each use, taking into account that in compact bone there is greater wear.



Pilot Drill

Diameter	Length	Item code
Ø 2.00 mm	6-13 mm	STD1S
Ø 2.00 mm	5-18 mm	STD1L

Dual-diameter short drill

Diameter	Length	Item code
Ø 2.20/2.60 mm	6-13 mm	STD2S
Ø 2.60/3.00 mm	6-13 mm	STD3S
Ø 3.00/3.40 mm	6-13 mm	STD4S
Ø 3.40/3.80 mm	6-13 mm	STD5S
Ø 3.80/4.20 mm	6-13 mm	STD6S
Ø 4.20/4.60 mm	6-13 mm	STD7S
Ø 4.60/5.00 mm	6-13 mm	STD8S
Ø 5.00/5.40 mm	6-13 mm	STD9
Ø 5.40/5.80 mm	6-13 mm	STD10

Dual-diameter long drill

Diameter	Length	Item code
Ø 2.20/2.60 mm	5-18 mm	STD2L
Ø 2.60/3.00 mm	5-18 mm	STD3L
Ø 3.00/3.40 mm	5-18 mm	STD4L
Ø 3.40/3.80 mm	5-18 mm	STD5L
Ø 3.80/4.20 mm	5-18 mm	STD6L
Ø 4.20/4.60 mm	5-18 mm	STD7L
Ø 4.60/5.00 mm	5-18 mm	STD8L

Short DRILL STOPS

STD1S	STG6N
STD2S	STG8N
STD3S	STG10N
	STG115N
STD4S	STG6R
STD5S	STG8R
STG6S	STG10R
	STG115R
STD7S	STG6W
STD8S	STG8W
STD9	STG10W
STD10	STG115W



Cortical Drill

Diameter	Item code
Ø 3.40 mm	BP35
Ø 3.65 mm	BP37
Ø 4.20 mm	BP43
Ø 4.90 mm	BP50
Ø 5.90 mm	BP60



GLOBALWIN drill protocol according to the type of bone

Indications for the drills according to the type of bone

SOFT BONE

Nominal dimensions	Ø MAX Endosseous	Ø Apical Spire	Drill diameters	Last Drill code	Drill for use in particularly corticalised bone
3.75	3.90	2.40	2.20/2.60	STD2	-
4.30	4.30	2.80	2.20/2.60	STD2	-
5.00	5.00	3.20	2.60/3.00	STD3	-
6.00	6.00	4.80	3.00/3.40	STD4	(BP60)

MEDIUM BONE

Nominal dimensions	Ø MAX Endosseous	Ø Apical Spire	Drill diameters	Last Drill code	Drill for use in particularly corticalised bone
3.75	3.90	2.40	2.60/3.00	STD3	(BP37)
4.30	4.30	2.80	3.00/3.40	STD4	(BP43)
5.00	5.00	3.20	3.80/4.20	STD6	(BP50)
6.00	6.00	4.80	4.60/5.00	STD8	(BP60)

HARD BONE

Nominal dimensions	Ø MAX Endosseous	Ø Apical Spire	Drill diameters	Last Drill code	Drill for use in particularly corticalised bone
3.75	3.90	2.40	3.00/3.40	STD4	BP37
4.30	4.30	2.80	3.40/3.80	STD5	BP43
5.00	5.00	3.20	4.20/4.60	STD7	BP50
6.00	6.00	4.80	5.00/5.40	STD9	BP60

GLOBALWIN SLIM drill protocol according to type of bone

Indications for the drills according to the type of bone

SOFT BONE

Nominal dimensions	Ø MAX Endosseous	Ø Apical Spire	Drill diameters	Last Drill code	Drill for use in particularly corticalised bone
2.90	3.10	1.80	2.20/2.60	STD2	-
3.30	3.50	1.80	2.20/2.60	STD2	-

MEDIUM BONE

Nominal dimensions	Ø MAX Endosseous	Ø Apical Spire	Drill diameters	Last Drill code	Drill for use in particularly corticalised bone
2.90	3.10	1.80	2.20/2.60	STD2	-
3.30	3.50	1.80	2.20/2.60	STD2	-

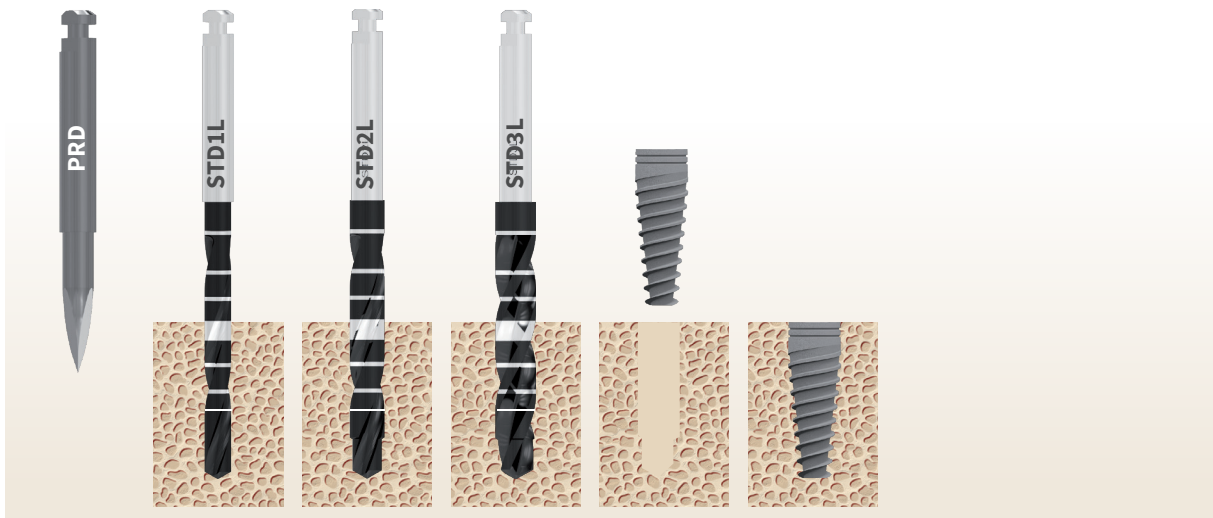
HARD BONE

Nominal dimensions	Ø MAX Endosseous	Ø Apical Spire	Drill diameters	Last Drill code	Drill for use in particularly corticalised bone
2.90	3.10	1.80	2.20/2.60	STD2	-
3.30	3.50	1.80	2.20/2.60	STD2	BP35

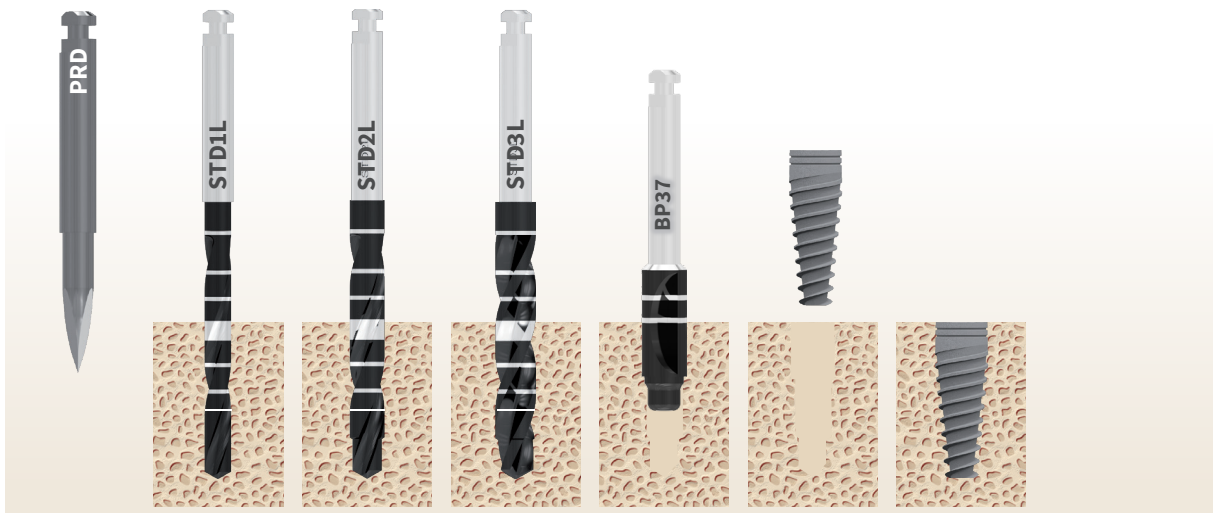
Use instrument 62LSI to remove the SLIM implant from the ampoule .
 After placement in the prepared site, proceed with screw-tightening with the dedicated mouter from the following instruments:
 62SC; 62MC; 62LC; 99SC; 99MC; 99LC.

Procedure for preparation of the implant site according to the type of bone

Implant diameter 3.75 x H 11.5 in SOFT BONE

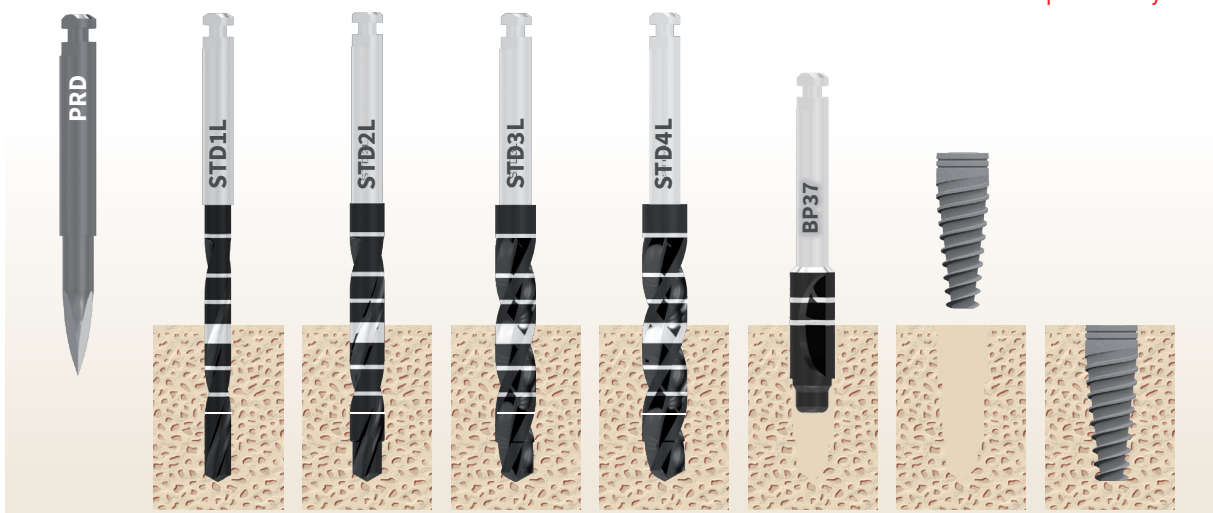


Implant diameter 3.75 x H 11.5 in MEDIUM BONE



Implant diameter 3.75 x H 11.5 in HARD BONE

! Use cortical drill BP.. for cases with particularly hard bone



GLOBALWIN Surgical Kit



Torque wrench
DTW
DTW75

Non-torque wrench
MTW

Manual adapter for non-torque wrench instruments
ADMTR

Manual adapter for contra-angle screwdriver
HASD

Short drill STOPS

Pilot Drills
STD1L
STD1S

Lance-shaped drill
PRD

Contra-Angle
DEX

Contra-angle screwdrivers
HSD20
HSD25
HSD30

Manual screwdrivers
DSD12
DSD16
DSD26

Mounter for Ball attachment
HMBLT

Mounter for Performing Abutment
HMPRA

Manual screwdrivers
MTRS
MTRM
MTRL

Contra-angle implant drivers
HMTRS
HMTRM
HMTRL

Dual-diameter drills
STD2L STD2S
STD3L STD3S
STD4L STD4S
STD5L STD5S
STD6L STD6S
STD7L STD7S
STD8L STD8S
STD9
STD10

Direction indicator and depth gauge
DIRS
DIRL

Cortical drills
BP35
BP37
BP43
BP50
BP60

PRD	STD1L	STD2L	STD3L	STD4L	STD5L	STD6L	STD7L	STD8L	DIRS	DIRL
	2.00	2.20/2.60	2.60/3.00	3.00/3.40	3.40/3.80	3.80/4.20	4.20/4.60	4.60/5.00	5.00/5.40	5.40/5.80
DEX	STD1S	STD2S	STD3S	STD4S	STD5S	STD6S	STD7S	STD8S	STD9	STD10
	HSD20	HSD25	HSD30		HMTRS	HMTRM	HMTRL	BP37	BP43	
	DSD12	DSD16	DSD26		MTRS	MTRM	MTRL	BP50	BP60	
	HMBLT	HMPRA								

Inserting the Implant

The implants are supplied sterile, in a transparent ampoule inside a colour-coded titanium container. The sterile ampoule is thermo-sealed inside a blister pack.

The direct coupling of the implant in its container is a specific feature of the GLOBALWIN implant, which:

- has reduced vertical dimension, facilitating insertion into the oral cavity by means of the insertion instruments
- never accidentally comes into contact with any materials other than titanium, thus avoiding possible contamination
- allows the implant to be engaged by the specific mounters, without further manoeuvring during software-assisted implantology

Packaging

It displays all the necessary information for immediate identification of the product, as well as the indicators required by law, in compliance with the standards that regulate medical devices.

The packaging adequately protects the product, allowing easy storage.

On the Ampoule:

- Product code
- Production batch

Packaging:

- Information leaflet
- Label with stickers for accurate patient data documentation:
 - 1 sticker for the clinical record
 - 1 for communication with the laboratory
 - 1 for the patient's Implant Card

On the Blister:

- Product code
- Production batch
- Sterilisation batch
- Sterilisation date
- Expiry date



1 Opening the Packaging

The non-sterile assistant first opens the outer packaging, then the blister pack, dropping the sterile ampoule onto the surgical tray without touching it. The sterile professional opens the ampoule by lifting the cap to which the implant cover screw is attached. The implant is housed inside the sterile ampoule. To remove it, use the appropriate instruments without turning it upside down.

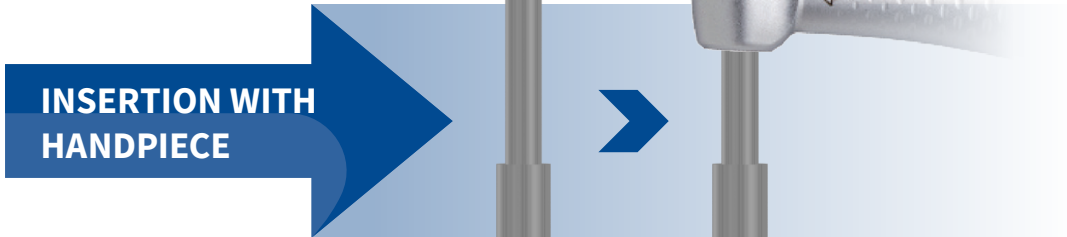
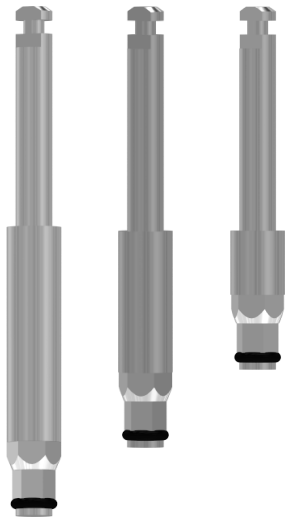
2 Extracting the implant

The implant is directly engaged inside the ampoule by the using the handpiece, manually or with a torque wrench, without breaking the sterile chain.

Inserting the implant with contra-angle or handpiece or manually

Contra-angle fastener

HMTRL HMTRM HMTRS



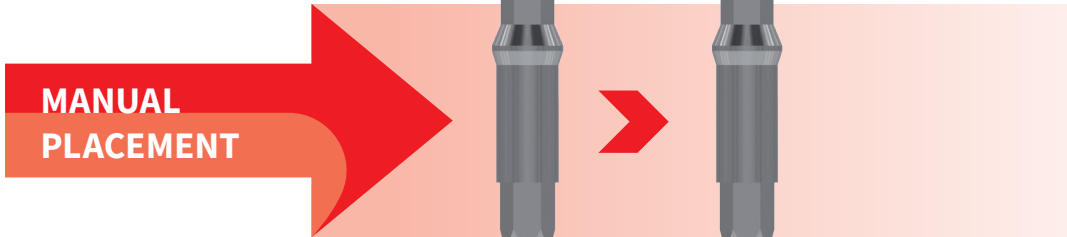
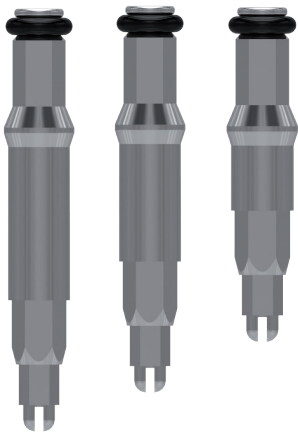
Non-torque wrench

MTW



Manual driver

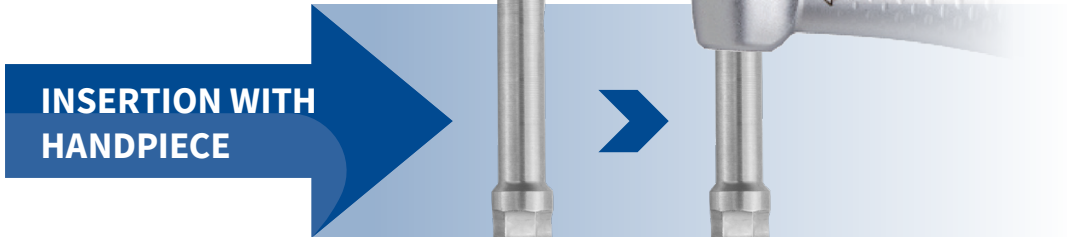
MTRL MTRM MTRS



Inserting the implant with contra-angle or handpiece or manually

Contra-angle fastener

99SC 99MC 99LC



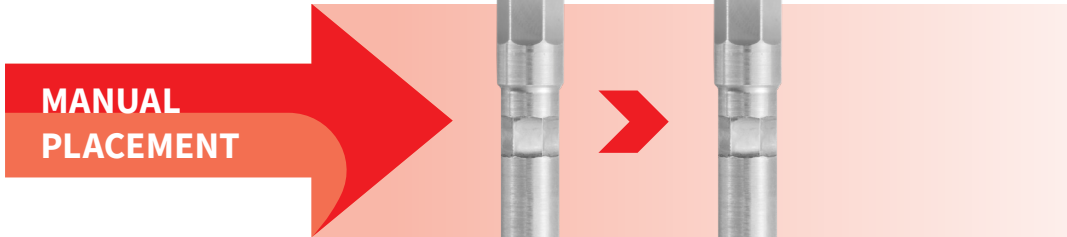
Non-torque wrench

MTW



Manual driver

62SC 62MC 62LC

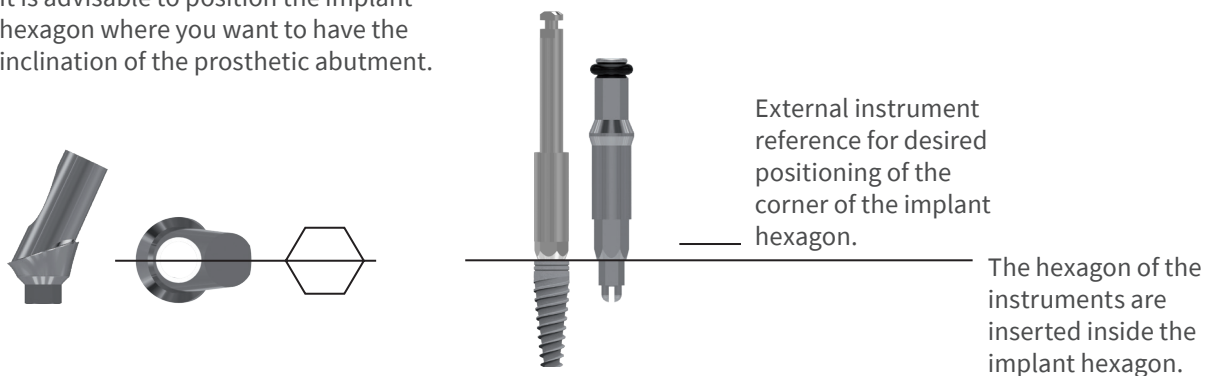


Tightening the Implants

Positioning of the implant hexagon

The correct positioning of the implant can be very important in case of prosthetic solutions with angled prosthetic abutments.

The inclination of the abutment angle falls toward the corner of the hexagon. It is advisable to position the implant hexagon where you want to have the inclination of the prosthetic abutment.



Recommendations:

- 1 Set the torque on the physiodispenser to 30 N/cm.
- 2 If during fitting, the implant stops at the beginning or in the middle, this means that the under-preparation is excessive for the type of bone. It is therefore advisable to remove the implant and store it in the ampoule, for reuse after passing the larger diameter drill through.
- 3 If a few coils are missing on fully mounting the implant, then proceed to the definitive mounting using the surgical ratchet wrench.

Rehabilitative technique for multi-unit screw-retained prostheses

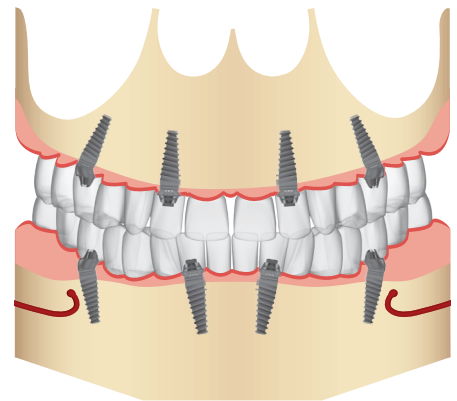
Teeth Just on 4

In order to offer satisfactory and economically viable restorative solutions to a significant portion of the population, we have developed specific surgical and prosthetic protocols for resolving cases with extensive edentulism the upper or lower jaws:

Teeth Just on 4 and Teeth Just on 6.

Clinical studies and research have shown that the inclined insertion of two distal implants is an effective and simple technique to compensate for any bone failure, thus expanding the prosthetic base in a stable and functional manner.

In the case of the mandible, this technique also protects the final portion of the arch, avoiding interference with the mandibular nerve. The Teeth Just On 4 or Teeth Just on 6 technique allows complete, permanent and stable arch rehabilitation, in many cases avoiding the necessity of bone regeneration procedures and the discomfort and cost to the patient involved.



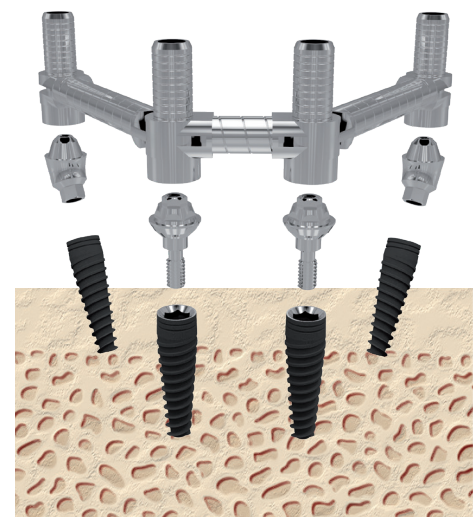
TEETH JUST ON 4 - GLOBALWIN Implants
For the complete, permanent and stable prosthetic rehabilitation of the lower arch on only 4 implants.

CAB Clip Abutment Bar

The **CAB** CLIP Abutment BAR device promotes the solidifying of dental implants by means of a Clip - Abutment - Bar combination applied to immediate and non-immediate loading, screw-retained prostheses, in line with the Teeth Just on 4/6 restorative technique protocol.

The CAB is used to build a passive titanium structure, to be implemented in the shortest time, in the context of immediate load application.

It represents a reinforcement of the temporary prosthesis, minimising the risk of fracturing that could lead to failure of the Implants.



USA

The patent issued for the CAB® by the US authority confirms its originality and innovative technological content.



European Union

International and European Patent
PCT/EP2011/072448
EP Patent no. 11425032.7



Bar preparation procedure

After placing the implants and their respective abutments from the PRAxxxx line, an impression is taken with the appropriate PRAA abutments.

Subsequently, the laboratory model is developed with analogues for PRAxxxx fitted. The AT... abutments are selected according to the shoulder height, allowing the bar to be parallel to the occlusal plane. Once the ATxx abutments are in place, each individual bar is cut using the appropriate CB instrument.

After cutting all the bars, the appropriate CF1 or CM1 Clip is inserted, and the entire structure is assembled by mounting it on the ATxx abutments and permanently fixing it to the latter with appropriate cements.

CAB Kit



CAB Components

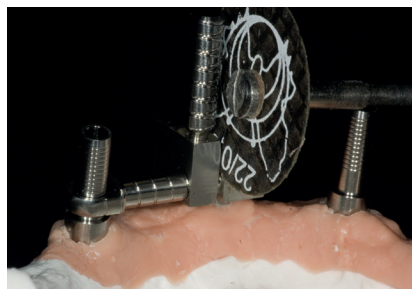
Code BTO Bar without Clip	
Code BT1 Retentive bar with Male clip, cylindrical hole and 1mm thickness	
Code BT2 Retentive bar with Male clip, cylindrical hole and 2mm thickness	
Code BT3 Retentive bar with male clip with elliptical hole and 2 mm thickness	
Code CM1 Male Clip with cylindrical hole and 1 mm thickness	
Code CM2 Male Clip with cylindrical hole and 2 mm thickness	
Code CM3 Male Clip with elliptical hole and 2 mm thickness	
Code CF1 Female Clip	
Code AT... CAB abutment shoulder where xx indicates variable shoulder height from 1.7 to 4.2 mm	
Code CB Cutter Bar	

Fully adjustable bar

Thanks to the cylindrical or elliptical geometry of the special clips, the Clip-Abutment connection allows extreme versatility of use even in the event of severe disparallelism. This feature makes it ideal for multi-unit screw-retained prostheses with immediate or deferred loading.



1 Measurement of the CAB bar with the help of the Cutter Bar device



2 Cutting the CAB bar with separating disc



3 The mounted CAB bar is easily positioned, even in the event of severe disparallelism

Manufactured by:

BIOSAF IN srl
info@biosafin.com
www.biosafin.com

Offices in Italy:

MILAN:
Via Cagliari 32/44
20060 - Trezzano Rosa (MI)
Zona Industriale
Tel. +39 02 90968692
Fax +39 02 90968541

ANCONA:
Via Tiraboschi, 36/G
60131 - Ancona (AN)
Tel. +39 071 2071897
Fax +39 071 203261

CODE 19 1 / ITA / VI - 2024



GLOBALWIN
I M P L A N T S Y S T E M

GLOBALWIN Medical devices are compliant with EC Directive 93/42 as amended

www.globalwin.eu



BIOSAF IN is certified to:

ISO 9001, which certifies the entire work process, from start to finish, further demonstrating our compliance with quality standards considered optimal for the protection of product Users – Professionals – and end users – Patients.

ISO 13485 specifically relevant to the quality of Medical Devices.