



# fixo

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**OXY Implant** is a dental implant system totally designed, developed and manufactured in Italy.

The specific company know-how, acquired during thirty years completely spent in researches for dental implantology innovative solutions, allows to keep the **OXY Implant** line devices constantly at the quality level required by the most advanced scientific literature. All this offers the Surgeon a variety of choices that allow to easily deal with even the most complicated clinical situations.

The pursuit of the highest quality, obtained through the careful selection of suppliers and raw materials, the collaboration with research centres and the constant dialogue with the best Italian and foreign Implantologists, results in the great long-term reliability of the **OXY Implant Dental System** with the advantage of the Doctors and Patients ease.

All the implants of the **OXY Implant** line are made of Titanium Grade 4 of European origin, with characteristics of high mechanical resistance resulting from a special cold wire-drawing process.

The prosthetic components are made of Titanium Grade 5 and the surgical instruments of a special stainless steel. The machines used to produce **Oxy Implant** devices are equipped with the best numerical control technology, which allows working with tolerances of a few microns, thus ensuring the excellent overall quality of the implant-abutment system.

The production, testing and packaging phases of all the **OXY Implant** line devices are developed entirely in the company, with the consequent possibility of a direct and constant control of the whole process by a highly skilled Team of Technicians.

The primary packaging of the implants is performed in a cleanroom to avoid any contamination, in compliance with the most stringent sectoral norms.

The renovated head office allows to welcome in an appropriate and modern way all the Customers who wish to observe how the process of realisation of implants, prosthetic components and surgical instruments develops. A large training room allows to organise for Dentists and Dental Technicians many training and refresher events which also represent a useful moment of dialogue between Manufacturer and Users. Their suggestions, derived from daily practice, allow indeed to continuously improve and innovate the **OXY Implant** system.

The medical devices of the **OXY Implant** system comply with the European Directive 93/42/EEC. The manufacturer Biomec S.r.l. has obtained the authorisation to sell from a European notified body and has been equipped with a quality system ISO 9001 and ISO 13485 since 1998.





**AMS** (Advanced Micro Surface) is the surface selected for the entire range of implants by **OXY Implant**. This surface goes far beyond the results of earlier machined surfaces or surfaces treated with acid and chemical passivation. The **AMS** treatment was developed to accelerate the biological response of cell adhesion, thus enhancing the osseointegration process and the final clinical outcome. **AMS** is obtained with processes of chemical etching, decontamination and a cold Argon plasma treatment. Together they create a new surface with a high degree of cleanliness characterised by a homogeneous micro-porosity of the order of a few microns, smaller than the cell size, so as to considerably increase the adhesion of the osteoblastic cells and to favour the process of osteogenesis.

All these factors are decisive in achieving the best bone-to-implant anchorage and a higher torque required for implant removal. The surface treatment of endosseous components is carried out by a specialised and certified company.



The 5000 X and 7500 X images show in detail the roughness obtained by means of the treatment: the interpeak distance is just a few microns, certainly smaller than the cell size, and accords with recent data about the effects of roughness size on the differentiation and behaviour of osteoblastic cells.

The cleanliness of the screw surface has been confirmed by an XPS analysis on the surface chemical composition. The analysed depth is about 5nm and provides a direct indication of the chemical composition of the material layers directly in contact with the bone.

According to the literature, the maximum concentration of Ti observable by means of XPS on the implant surface after treatment is 14-19%. A percentage of Titanium higher than 10% can be considered satisfactory. The detected amount of Titanium on **OXY** implants is 18%, a value close to the maximum obtainable percentage.



Citotoxicity tests have been carried out in order to confirm the absence of toxicity induced by the processed screws. The possible presence of dead cells, multinucleated giant cells and general abnormalities in cell morphology was evaluated by comparing the data obtained at the cell layer in contact with the negative control (gold cylinder the same size as the implants) and with the positive control (gutta-percha cylinder).

After being observed under a microscope, the cells were fixed with fixative solution, coloured and photographed. The image relates to the results of tests carried out on experimental samples of the **OXY Implant** line.

All the observations reveal a situation in line with that of the negative control, that is they confirm the absence of toxic effects.

The surface treatment of the **OXY** implants guarantees:

- osteoblast adhesion to the implant surface
- no adverse effect on osteoblast adhesion and growth nor on the surface colonisation.

#### In conclusion:

- · the surface treatment process implemented causes a morphological alteration of the processed screws
- . the roughness obtained conforms to what is deemed appropriate to enhance the healing process of bone and osseointegration, at the current state of knowledge
- the implemented process and the following decontamination step allows the complete removal of residues arising from processing and the production of surfaces free of contaminants and foreign deposits
- · implants processed with this treatment do not show cytotoxicity effects
- · validated and checked periodically, 100% visual inspection and electron microscope analysis on some samples of each treatment batch.

The implants outer package of **OXY Implant** is made of cardboard and has a convenient tear-off opening system.

The design of the package contains the name of the implant line, the angulation of the Fixo MUA head and the colour coding.

The external stickers of the package indicate all the specific data of the implant: description, reference number, production batch, expiry date and manufacturer.

Inside the package there is the sterile tube containing the implant assembled to the mounter, the instructions for use and 3 stickers indicating all the specific data of the implant, which should be applied respectively on the medical record, on the patient's implant passport and on any additional documentation.





The prosthetic components and the optional or spare surgical instruments are packaged in thermosealed polyethylene bags, with an adhesive label showing all the data of the device: description, reference and batch numbers, colour coding, manufacturer and specific standard symbols for each item.

The prosthetic components and surgical instruments are supplied NON-STERILE and must be sterilised before use.

All the implants made by **OXY Implant** are contained in a plastic material tube sealed with a screw cap with safety ring, tested to guarantee a 5-year sterility.

The sterilisation is performed with BETA rays irradiation validated process, guaranteed and subjected to periodic controls.

### **MOUNT FREE - OXY CLAMP SYSTEM:**

- the mounter preassembled on the implant is housed in a plastic support with titanium core
- allows to see the implant before opening the tube and prevents the movements of the implant facilitating the extraction

### Extraction of the implant in 4 simple steps:



place the Oxy Clamp

2.

on a sterile field



to the mechanical adapter

press the lower part of the Oxy Clamp to release the mounter/implant

# fixo

**Fixo line** consists of **single-piece** implants, ideal for the Surgeon who wants to perform a fast immediate load rehabilitation thanks to the **integrated** multi-unit abutment. Three angulations are available - 0°, **17**° and **30**° - to allow the surgery and prosthetic team to solve the disparallelisms resulting from the straight and angled implants placement, fully meeting the aesthetic and functional requirements.

The **small** diameter of **Fixo line** implants, plus the perfect **coaxiality** of the fixture-mua monobloc, make them ideal for use in **guided surgery**. Thanks to the characteristics above, there is **no interference** during their insertion through the sleeves of the surgical template and during template removal.

The positioning of the implant with the screw-hole direction of the multi-unit abutment perfectly **corresponding** to the design phase planning is ensured by a mounting system conceived and tested in collaboration with **3Diemme** software-house, in which the stated goal is perfectly centred in the three dimensions by matching precise and evident spatial references obtained through special pre-assembled mounter.

However, the tools available in the dedicated surgical kit allow Fixo to be easily used also in **conventional surgery**: a specific **guide** provides support in creating the implant site with the best angulation, while the special **pins** allow to evaluate previously the most appropriate implant angulation to be used in each single case.

The particular anatomical shape of the neck (pink coloured to favour the aesthetic harmonisation with soft tissues), in addition to the already mentioned small diameter, favour an optimal and fast soft tissues **healing**.

It is evident that, in accordance with a widely consolidated clinical literature, the **absence** of implant-abutment connection cancels the possibility of **micromovements** and consequently helps avoiding bacterial infiltrations.

### PRE-ASSEMBLED MOUNTER

The special pre-assembled mounters facilitate the implant placement, even with an angled abutment, allowing to perfectly match the screwing to the axis of the surgical site.

The Ø 5 mm mounter allows the use in **guided surgery** of both **Fixo** and **Fixo Mini** and, thanks to the appropriate template sleeve, also the positioning corresponding to the one planned with the software.

#### Mounter colour coding:











The chamfer diameter of the integrated abutment (0° and 17°) is only **4.0 mm**: Fixo Mini is therefore ideal for use in areas of high **aesthetic** value. Its small diameters allow for use only in low stress incisive areas.

The peculiar shape does not however compromise its mechanical strength and allows the use of a **M1.8** prosthetic screw with tightening to **30 Ncm**.





# Ø 3.0 mm

mini

|              | 0°         |
|--------------|------------|
| 2mm ⊥        |            |
| Length       | Ref.       |
| <u>10 mm</u> | F4M3000100 |
| 11.5 mm      | F4M3000115 |
| 13 mm        | F4M3000130 |





mini

|         | 0°          |
|---------|-------------|
| 2 mm I  | <b>)</b> [L |
| Length  | Ref.        |
| 8.5 mm  | F4M3500085  |
| 10 mm   | F4M3500100  |
| 11.5 mm | F4M3500115  |
| 13 mm   | F4M3500130  |

F4M3500150



| Length         | Ref.       |
|----------------|------------|
| 8.5 mm         | F4M3517085 |
| 10 mm          | F4M3517100 |
| <u>11.5 mm</u> | F4M3517115 |
| <u>13 mm</u>   | F4M3517130 |
| 15 mm          | F4M3517150 |

The nominal length L is measured from the apex up to 0,5 mm above the treated section.

<u>15 mm</u>



### Ø 3.5 mm

short

|                | 0°          |
|----------------|-------------|
| 2 mm I         |             |
| Length         | Ref.        |
| 8.5 mm         | F4G3500085S |
| <u>10 mm</u>   | F4G3500100S |
| <u>11.5 mm</u> | F4G3500115S |
| <u>13 mm</u>   | F4G3500130S |
| 15 mm          | F4G3500150S |



| Length       | Ref.        |
|--------------|-------------|
| 8.5 mm       | F4G3517085S |
| <u>10 mm</u> | F4G3517100S |
| 11.5 mm      | F4G3517115S |
| <u>13 mm</u> | F4G3517130S |
| <u>15 mm</u> | F4G3517150S |

|        | 30°                   |
|--------|-----------------------|
| 3 mm ∏ | <b>P</b> <sub>T</sub> |
|        |                       |

| Length       | Ref.        |
|--------------|-------------|
| 10 mm        | F4G3530100S |
| 11.5 mm      | F4G3530115S |
| 13 mm        | F4G3530130S |
| <u>15 mm</u> | F4G3530150S |

Ø 3.5 mm long

|              | 0°          |
|--------------|-------------|
| 3 mm ]       |             |
| Length       | Ref.        |
| <u>10 mm</u> | F4G3500100L |
| 11.5 mm      | F4G3500115L |
| 13 mm        | F4G3500130L |
| 15 mm        | F4G3500150L |



| Length  | Ref.        |
|---------|-------------|
| 10 mm   | F4G3517100L |
| 11.5 mm | F4G3517115L |
| 13 mm   | F4G3517130L |
| 15 mm   | F4G3517150L |



| Length       | Ref.        |
|--------------|-------------|
| 10 mm        | F4G3530100L |
| 11.5 mm      | F4G3530115L |
| <u>13 mm</u> | F4G3530130L |
| 15 mm        | F4G3530150L |



# Ø 4.0 mm

short

|                         | 0°  |
|-------------------------|---|
| 2 mm I                  |   |
|                         |   |
| Length                  | Ref.                                      |
| Length<br>7 mm          | <b>Ref.</b><br>F4G4000070S                |
| _                       |   |
| 7 mm                    | F4G4000070S                               |
| 7 mm<br>8.5 mm          | F4G4000070S<br>F4G4000085S                |
| 7 mm<br>8.5 mm<br>10 mm | F4G4000070S<br>F4G4000085S<br>F4G4000100S |

F4G4000170S

<u>17 mm</u>



| Length  | Ref.        |
|---------|-------------|
| 7 mm    | F4G4017070S |
| 8.5 mm  | F4G4017085S |
| 10 mm   | F4G4017100S |
| 11.5 mm | F4G4017115S |
| 13 mm   | F4G4017130S |
| 15 mm   | F4G4017150S |
| 17 mm   | F4G4017170S |



| Length       | Ref.        |
|--------------|-------------|
| <u>10 mm</u> | F4G4030100S |
| 11.5 mm      | F4G4030115S |
| <u>13 mm</u> | F4G4030130S |
| 15 mm        | F4G4030150S |
| 17 mm        | F4G4030170S |

Ø 4.0 mm

long

|              | 0°          |
|--------------|-------------|
| 3 mm ]       |             |
| Length       | Ref.        |
| 10 mm        | F4G4000100L |
| 11.5 mm      | F4G4000115L |
| <u>13 mm</u> | F4G4000130L |
| 15 mm        | F4G4000150L |



| Length       | Ref.        |
|--------------|-------------|
| 10 mm        | F4G4017100L |
| 11.5 mm      | F4G4017115L |
| <u>13 mm</u> | F4G4017130L |
| <u>15 mm</u> | F4G4017150L |



| Length         | Ref.        |
|----------------|-------------|
| 10 mm          | F4G4030100L |
| <u>11.5 mm</u> | F4G4030115L |
| <u>13 mm</u>   | F4G4030130L |
| 15 mm          | F4G4030150L |



# Ø 4.5 mm

short

| 0°     |   |
|--------|---|
| 2 mm I |   |
| Length | R |

| Length         | Ref.        |
|----------------|-------------|
| 7 mm           | F4G4500070S |
| <u>8.5 mm</u>  | F4G4500085S |
| <u>10 mm</u>   | F4G4500100S |
| <u>11.5 mm</u> | F4G4500115S |
| <u>13 mm</u>   | F4G4500130S |
| <u>15 mm</u>   | F4G4500150S |



| Length  | Ref.        |
|---------|-------------|
| 7 mm    | F4G4517070S |
| 8.5 mm  | F4G4517085S |
| 10 mm   | F4G4517100S |
| 11.5 mm | F4G4517115S |
| 13 mm   | F4G4517130S |
| 15 mm   | F4G4517150S |

|        | 30° |
|--------|-----|
| 3 mm ] |     |
|        | 1   |

| Length         | Ref.        |
|----------------|-------------|
| <u>10 mm</u>   | F4G4530100S |
| <u>11.5 mm</u> | F4G4530115S |
| <u>13 mm</u>   | F4G4530130S |
| 15 mm          | F4G4530150S |
|                |             |

Ø 4.5 mm

long

|              | 0°          |
|--------------|-------------|
| 3 mm ]       |             |
| Length       | Ref.        |
| 10 mm        | F4G4500100L |
| 11.5 mm      | F4G4500115L |
| <u>13 mm</u> | F4G4500130L |
| 15 mm        | F4G4500150L |



| Length  | Ref.        |
|---------|-------------|
| 10 mm   | F4G4517100L |
| 11.5 mm | F4G4517115L |
| 13 mm   | F4G4517130L |
| 15 mm   | F4G4517150L |



| Length         | Ref.        |
|----------------|-------------|
| <u>10 mm</u>   | F4G4530100L |
| <u>11.5 mm</u> | F4G4530115L |
| <u>13 mm</u>   | F4G4530130L |
| <u>15 mm</u>   | F4G4530150L |





Mechanical screwdriver SESD or MESD must be ordered separately.

MESD

Д

F4GCC

# SURGICAL INSTRUMENTS



The drills for **Fixo** and **Fixo mini** implants are designed and manufactured with the aim of ensuring the constant efficiency and durability. These prerogatives are realised firstly thanks to the use of absolute quality materials as the special hardened stainless steel used for their manufacture. Finishing processes of last generation complete the production cycle.

All the drills are **Black Diamond** coated, a perfectly biocompatible material which increases their superficial hardness and decreases the generated friction forces. This process increases therefore considerably the cutting power and consequently reduces the risk of the bone overheating during surgery.

Their morphology is cylindrical with a smaller diameter step to provide a surgical socket that follows accurately the shape of the **Fixo** and **Fixo mini** implants, more conical in the apical area.

The drills are sequential with a 0.3 mm step between the successive diameters (2.9 - 3.2 - 3.5 - 3.8 and 4.1 mm) to create a surgical socket corresponding to the diameter of the implant core or to underprepare or overprepare it according of the bone density characteristics.

In order to facilitate the Surgeon's work, they are graduated with laser markings to indicate the length of the corresponding implant to be inserted. For the same reason they can also be provided with titanium depth stoppers.

Also, the diameter of the drill is well highlighted thanks to a specific laser marking.

The colour of the ring on the shank of the instrument allows to easily locate the housing of the surgical kit in which to place it: it is in fact characterised by the same coding.

It is important to remember that the tip of the drill increases of 0.5 mm the nominal length of the instrument. Taking always this into account, will be possible to avoid the anatomical structures damage especially during use in areas close to the maxillary sinus or to the mandibular channel.



# SURGICAL INSTRUMENTS





The surgical kits are designed with the purpose to enhance the compactness and ease of use.

The arrangement of the instruments and the colour coding determines a logical and intuitive instruments use process during the successive steps of the intervention.

ref. TRPSKFIXO

DRILL EXTENDER

surgical instrument kit

Implant

To facilitate their maintaining, the boxes are made of autoclavable and autosanitising plastic.

\_\_ ref. TRF4G additional surgical kit: ref. TREIPSK ref. TREIPSCLS

FDO

NSERTER

PROSTETPUC DRIVER



### for ø 3.0 mm FIXO MINI implants



Important: the Ø 2.0 mm drill is included in the kit, and the Ø 1.6 mm drill (ref. 3DM006131615) must be purchased separately.

### for ø 3.5 mm FIXO MINI implants





## 

### for ø 3.5 mm FIXO implants





**FIXO** DRILLING SEQUENCE

### for ø 4.0 mm FIXO implants

### for ø 4.5 mm FIXO implants









### )GS )GS







MCF4G

T

CPINGS

SCIEWS blue disc Hardened stainless steel hexagonal key 1.25 mm

manual

for

fixing

Stainless steel

pin sleeve

screwdriver



driver converter square 4x4

| grey disc |           |       |
|-----------|-----------|-------|
| Hardened  | stainless | steel |



XCMRC8 CMRC8 extrashort short

28

### bite gauge

Stainless steel



BITEGAUGEPS

### torque ratchet

Stainless steel driver D8 torque 10÷70 Ncm



TR8

## feeler gauge



Stainless steel

F4G090

| C | ſ      | 2      |  |
|---|--------|--------|--|
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| F | _      | _      |  |
| C | _      | כ      |  |
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