



TECHNICAL OPERATIONS MANUAL

SURGICAL PROCEDURES
FOR IML IMPLANT SYSTEMS:

UNIVERSE AND UNIVERSE 2.9

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TECHNICAL OPERATIONS MANUAL FOR SURGICAL PROCEDURES

This manual contains basic information for dental professionals regarding the surgical procedures for the UNIVERSE and UNIVERSE 2.9 implant systems, illustrating the essential steps for the preparation of the osteotomy and the placement of the IML UNIVERSE and UNIVERSE 2.9 implants.

It is intended for use by dental professionals who have undergone adequate professional training.

These IML devices are intended for use by properly trained professionals, who shall assume full responsibility for their actions. Under no circumstances may IML SA be held liable for any errors and/or damage that may result from clinical treatment due to the incorrect use of the devices.

IML IMPLANT SYSTEMS

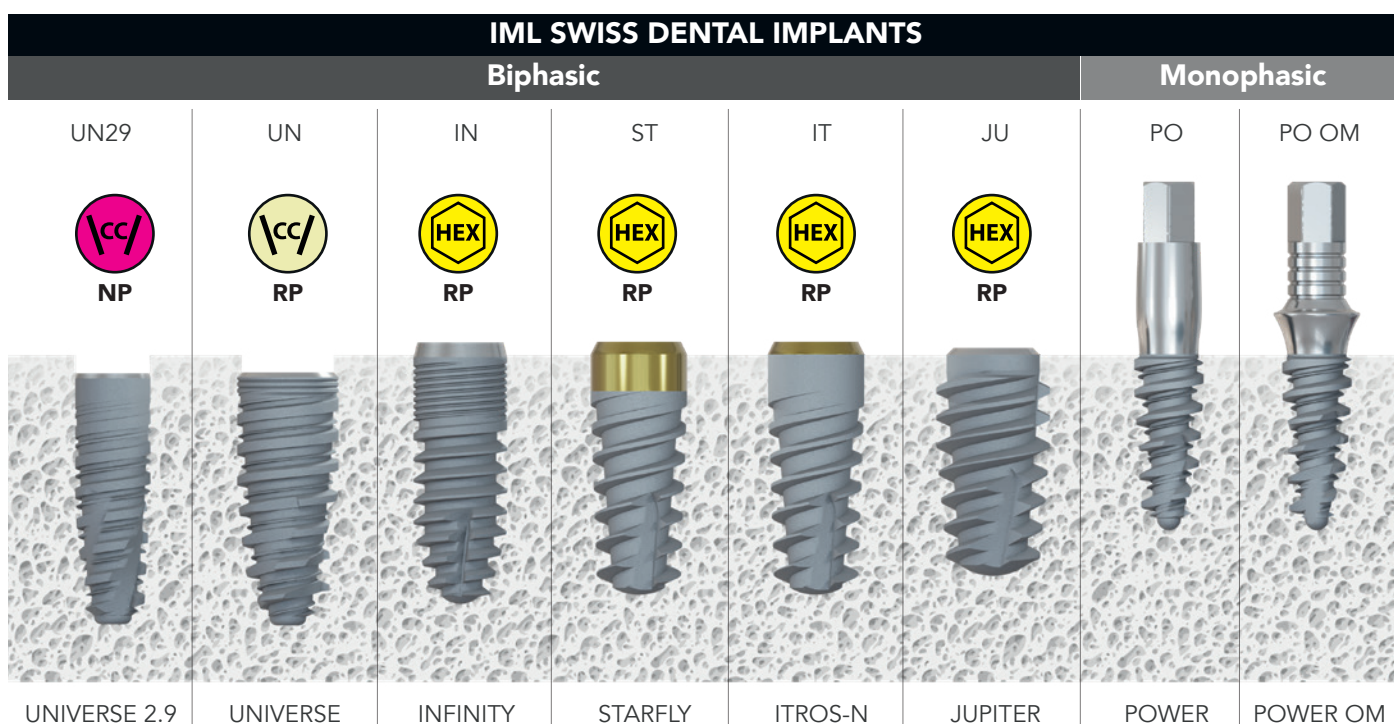
IML Swiss Dental Implants offers various biphasic and monophasic implant systems: UNIVERSE, UNIVERSE 2.9, STARFLY, ITROS-N, INFINITY, JUPITER, POWER and POWER OM.

The full range of IML implants allows oral surgeons to handle all kinds of different clinical cases. In particular, IML implants are atraumatic in order to avoid the risks associated with overheating the bone and post-operative oedema.

IML implant systems can be used in cases of total maxillary or mandibular edentulism for anchoring complete dentures or fixed prostheses, to create terminal or intermediate abutments for bridges and individual teeth. IML fixtures (implants) exploit the advantages of both conometric and hexagonal connections.

Each surgeon will be able to select and manage the implant line with the respective connection based on the various clinical situations.




The company offers a wide range of prosthetic components for both Implant replica and digital prosthetics.



IML Swiss Dental Implants are made of grade 4 titanium, and are supplied in sterile ampoules with a guaranteed seal, ready for implantation. The surface is treated using the SL treatment method.

A unified colour code simplifies the identification of tools and implants for the available platforms.

COLOUR CODE

	CC NP	Conical Connection for Ø2.9	UN29
	CC RP	Conical Connection for Ø3.4 to Ø5.0	UN
	HEX RP	Hexagonal connection for Ø3.5 to Ø6.0	ST, IN, IT, JU

CONTRAINDICATIONS

Implant therapy is not recommended in the following cases:

1) patients suffering from the following general conditions: cachexia, diabetes, hyperthyroidism, anaemia, leucopathies, haemorrhagic diathesis, osteomalacia, osteitis deformans, osteogenesis imperfecta, immune system disorders, and any systemic diseases or pharmacological therapies that could impair tissue repair capabilities, such as the use of immunosuppressants and corticosteroids. Patients suffering from neurotic or psychotic illnesses, or with mental instability, and patients who abuse tobacco, alcohol, or drugs should also be excluded.

Cardiac and circulatory diseases are a general surgical contraindication, and are therefore also a contraindication to implant therapy. Surgery should likewise be avoided during pregnancy.

2) patients suffering from the following local conditions: inadequate bone quantity, presence of soft tissue lesions (such as leukoplasias, lichen, stomatitis, epulidia, etc.), hard tissue lesions (such as cysts, granulomas, root remnants, inflammatory changes, etc.). Inadequate oral hygiene. Previous or current radiation therapy. Xerostomia. Bruxism and inadequate occlusal conditions.

3) patient age: in adolescents, implants should only be considered after the completion of bone growth.

RECOMMENDATIONS

Dental implants should only be considered for patients with a good level of oral hygiene, who are sufficiently motivated and cooperative. Each site where an implant is to be placed must have undergone an adequate diagnostic, clinical, and radiological evaluation. Incorrect procedures can lead to implant loss and biological damage. Adequate antibiotic coverage during the surgical and post-surgical phases is recommended.

The UNIVERSE and UNIVERSE 2.9 implants must be used with instruments specially designed for oral implantology, and must only be prothesised with original IML SA components.

The incorrect use of the components or the use of non-original components will immediately invalidate the warranty.

The patient must receive adequate instructions on the use and maintenance of the prosthesis, and the attending physician must carry out half-yearly check-ups and maintenance.

The slower the resorption of the supporting bone, the longer the lifespan of the entire implant-retained reconstruction.

When placing the implants, IML recommends respecting the biological width of 4mm from the end of the mucosa to the implant.

It has been shown that some resorption is physiological (Albrektsson, 1987), but poor oral hygiene can lead to increased losses due to infection, which is why it is important for patients to be made aware of the importance of maintaining good oral hygiene, and to be called back periodically for check-ups.

Implant mobility, sensitivity to percussion, bone loss, and infection are all indicators of a failing implant that needs to be removed.

WARNINGS

The surgery for the placement of the implants may be followed by certain complications: ecchymosis, haemorrhage, haematoma, soft tissue dehiscence, delayed healing, inflammation, infection, paresthesia, hyperesthesia, anaesthesia, chronic pain due to the implant, perforation of the maxillary sinus, injury to anatomical structures (nerve bundles and vessels), alveolar atrophy in the maxilla or mandible, oroantral or oronasal fistulas, damage to the adjoining dentition, bone fractures breakage.

Delayed complications can arise in the event of prosthetic overload, such as fracture of the prosthetic superstructure, implant fracture, loosening of prosthetic connection screws, and loss of integration. Other possible complications include aesthetic imperfections and peri-implantitis.

The surgical procedure for the use of IML SA products is highly specialised, and the use of these products is therefore restricted exclusively to dental professionals and experts. If the practitioner feels that he or she does not have the appropriate knowledge, he or she should attend appropriate training courses prior to using these products.

The surgical procedures described are to be considered standard indications that can be adapted to any particular practical needs and situations that may arise, also depending on the ability, experience, and diagnosis made by the legally qualified physician.

The product's use and the procedure followed are beyond the manufacturer's control.

The responsibility for the correct and appropriate use of the tools and products therefore lies with the user.

The UNIVERSE and UNIVERSE 2.9 implant systems are subject to constant research and development.

We rely on a leading network of opinion leaders and professors, thanks to whom the implant systems have achieved the highest standards in terms of quality and functionality.

IML SA therefore reserves the right to make any design and production changes deemed appropriate.

Check for product updates at the website www.Impl.swiss.

The UNIVERSE and UNIVERSE 2.9 implant fixtures are implantable-type medical devices intended for long-term use, which serve to replacing the natural roots of missing teeth. All the implants are sold in sterile disposable packaging. The coronal part of the implants have a connection designed to mount an implant abutment, in order to support a dental prosthesis.

The UNIVERSE and UNIVERSE 2.9 implants can be placed in already edentulous sites or in post-extraction sites, either immediately (implant insertion at the same time as tooth or root removal) or at a later time (a period of about 8 weeks is normally allowed to elapse between extraction and implant fixture insertion).

All the fixtures are sold in complete packages, complete with their respective screw caps.

The screw caps are also medical devices, and are intended to remain in the oral cavity for up to 30 days. The screw caps are also available separately.

METHOD OF USE

Two main surgical techniques are utilised:

- Two stage: carried out in two phases, the first being the placement of the implant, the covering of the connection with a screw cap, and suturing, and the second being the reopening of the mucosa after 2-6 months and the mounting of the prosthesis;
- One stage: implant placement, and closure of the connection with a transmucosal healing abutment instead of a screw cap. Alternatively, if therapeutically feasible, the implant can be immediately loaded with a suitable dental abutment, either temporary or permanent, as deemed appropriate.

The implants are inserted into the bone following surgical protocols that take into account the quantity and quality of the recipient bone, the implant or type of prosthesis it will support, and the possible need for regenerative therapies. A site is created in the patient's bone (at the site 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 compactors, or others (MAGNETIC MALLETT).

The conditions necessary for successful implantation are the following:

- presence of a certain quantity of bone;
- good periodontal (gingival) support;
- absence of bruxism (teeth grinding) or severe malocclusion;
- presence of good occlusal balance (correct masticatory occlusal plane).

The UNIVERSE implants have been tested in a wide range of clinical situations:

- standard operating procedures where double or single-stage surgery is involved;
- early and immediate loading;
- use in conjunction with regenerative therapies;
- post-extraction situations, even in combination with immediate loading.

Masticatory loading with fixed prostheses generally occurs later, after 2 to 3 months for the mandible, and after 4 to 6 months for the maxilla. In some, but not all cases, the immediate loading of the implants is also possible; to do so requires good primary stability, zero mobility, or mobility in the order of just a few microns. The bone-implant interface must therefore be of the order of microns, otherwise the implant risks being fibro-integrated.

PART INFORMATION 121DD3SCB02362 TI 6AL 4V ELI Custom Tolerance CG Bar - 6,0 mm (0.2362") Dia. Specifications: ASTM F 136 Rev: 13; ISO 5832-3 Rev: 2016; EN 10204 3.1 Rev: 04; AMS 4930 Rev: L; AMS 6932 Rev: C; ASTM B 348 Gr23 Rev: 19; NF A47-410 Rev: 1983; EN 4267 Rev: 2001 Size: 6,0 mm (0.2362") Dia. h7 (+0" / -0.00047") Length: 3,0 m (118.1") +152 mm / -0 mm (+6" / -0") Option to ship max 10% shorts down to 1.8m (6')											
Chemical Report (WT.%)											
Heat	AL T	AL B	C T	C B	Fe T	Fe B	N T	N B	O T	O B	
H34167	6.08	6.24	.018	.016	.18	.17	.009	.011	.11	.12	
V T	V B	Y T	Y B	Ti	Ot B	TOE					
3.97	4.05	<.0004	<.0004	BAL	<.10	<.30					
Hydrogen (As Shipped)											
Hydrogen (%) 0.0026											
As Shipped Properties											
UTS #1 (Mpa)			YS 0.2% #1 (Mpa)			EL #1 (%)			RA #1 (%)		
1004			887			18			46		
Hardness (HRC) 31											
Metallography Results											
Microstructure Alpha-Beta, Similar to ISO 20150 Plate: A1 Alpha Case Material Free of Alpha Case											
Melt Origin						Bt Tr °F					
USA						1780					
Melt Source						Bt Tr °C					
TIMET						971					
Certification Information											
As Shipped Condition Annealed 1300°F (704°C) 2 Hours A/C											

Titanium Grade 5:

93/42/EEC has established the following values for:

- Yield stress (YS):

795 MPa

-tensile strength (UTS):

860 MPa

The values found in titanium used by IML:

YS: 887 MPa vs 795 MPa =+11%.

UTS: 1004MPa vs 860 MPa=+12%.

SURFACE

The SL IML treatment is technically comparable to even the best SLAs™ documented in the literature. It is manufactured using a sandblasting technique with a technology that allows for maximum treatment consistency. This is followed by etching with acid solutions. The sandblasting generates a macro-roughness on the surface of the implant, which is superimposed with a micro-roughness obtained through the acid-etching process. The resulting surface topography generates a structure suitable for the anchoring of osteoblast cells, and promotes the implant’s optimal integration with the bone tissue.

CELL ADHESION

The physico-chemical properties of the material surfaces play a key role in determining the successful placement of implant devices at the bone interface. Surface topography (in terms of roughness and porosity type) affects cell adhesion, proliferation, and differentiation: the structural details and morphology of the cells are the response to stimuli from cell-surface contact. Based on these considerations, we evaluated the adhesion of murine mesenchymal stem cells (D1), which represent the best model in this field of application. The strategic decision to use these cells arose from the realisation that tumour-derived cells (e.g. SaOS-2) are not the best tool for assessing cell “well-being” in this kind of study. Although SaOS-2 cells share some of the same properties as non-transformed osteoblasts, they remain a tumour-derived lineage. Consequently, the surface of the analysed implant appears to allow for the osseointegration of the implant. The representative images obtained and the evaluation made by the operator during the analysis reveal the uniformity of growth and cell adhesion over the entire implant (thus excluding the presence of any zones or areas with quality defects). In particular, the UNIVERSE Conical Implant shows high levels of cell adhesion. Furthermore, by marking the nuclei, it can be seen that the cells are already growing and multiplying in number 24 hours after plating.

ROUGHNESS TEST ON 18/10/2023

Roughness consists of the various irregularities (microgeometric errors) left on the surface of a material by the preparation process. In order to determine the roughness, the profile is surveyed for a certain length L, called the base or sampling length. A line parallel to the theoretical profile can be defined along the length of the measurement and the profile thus determined, so that the sum of the peaks with respect to

the same is equal to that of the valleys. The parameter characterising a real surface is the average roughness R_a (S_a in the case of a 3D surface), which represents the arithmetic mean value of the absolute values of the deviations $|y|$ of the real profile from the mean line.

The determination of the R_a parameter alone is insufficient to characterise a surface, and it is therefore also important to measure other parameters, such as:

1) Skewness parameter (R_{sk}), which measures the asymmetry of the density function (indicative of predominant symmetry):

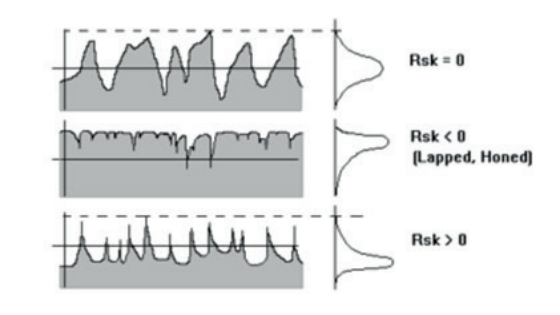


Figure 1: R_{sk} parameter

The R_{sk} parameter can assume various values:

- $R_{sk} = 0$: the distribution around the mean will follow a Gaussian curve;
- $R_{sk} < 0$: the distribution will be negative, and a full profile will therefore be obtained;
- $R_{sk} > 0$: the distribution will be positive, and the profile will have various peaks.

2) Kurtosis parameter (R_{ku}), equivalent to the peak density of the profile (indicative of indentation densities):

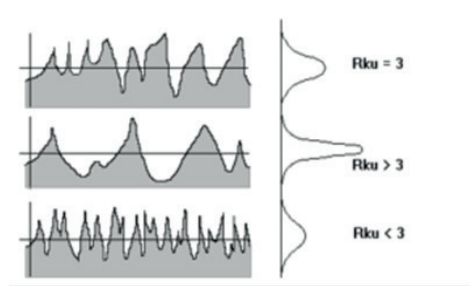


Figure 2: R_{ku} parameter

The R_{ku} parameter can assume various values:

- $R_{ku} = 3$: the distribution will follow the Gaussian curve;
- $R_{ku} < 3$: the distribution will tend to be more rounded than a Gaussian curve;
- $R_{ku} > 3$: the distribution will tend to be more pointed than a Gaussian curve.

SURFACE ROUGHNESS

Figures 3, 4 and 5 respectively show the reconstruction of the surface, the three-dimensional mapping, and a two-dimensional profile of the SAMPLE. Table 1 contains the values of the roughness parameters obtained.



Figure 3: Reconstruction of the sample surface

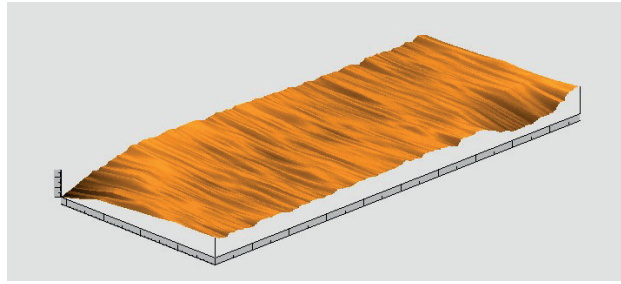


Figure 4: Three-dimensional view of the sample surface.

	H10		
	Sa (μm)	Ssk	Sku
	1.41	-0.08	2.82
	1.43	-0.07	3.07
	1.32	0.22	3.19
	1.29	0.16	3.25
	1.41	-0.15	2.97
media	1.372	0.016	3.060
dev. Stand	0.063	0.163	0.172
	Ra (μm)	Rsk	Rku
	0.99	0.01	2.98
	0.96	0.14	3.11
	0.97	-0.05	3.04
	1.01	0.24	3.15
	1.11	0.03	2.94
media	1.008	0.074	3.044
dev. Stand	0.060	0.115	0.087

Table 1: Surface parameters of the implant

As far as the Rsk parameter is concerned, the sample shows average values close to zero; being slightly positive values, they denote a surface with more peaks than valleys. For the Rku parameter, the samples show a value slightly above 3, thus indicating a regular surface.

ANALYSIS OF THE WETTABILITY OF THE IMPLANT SURFACE (ISSUE DATE 18/10/2023)

Wettability is defined as the tendency of one fluid to spread on or adhere to a solid surface in the presence of other immiscible fluids. The tendency of a liquid to spread on the surface of a solid is an indication of the wettability characteristics of the liquid with respect to the solid, and can be expressed more conveniently by measuring the angle of contact at the liquid-solid surface. The degree of the solid's hydrophilicity or lipophilicity can be assessed based on the polarity of the liquid utilised. Double-distilled water is commonly used to assess hydrophilicity, while apolar solvents, such as diiodomethane, are used to assess the degree of lipophilicity. If the contact angle is less than 90° , the surface can be defined as wettable. If the contact angle is greater than 90° , however, the surfaces are considered non-wettable. When the liquid used for the wettability measurements is water, the surfaces are respectively referred to as hydrophilic and hydrophobic.

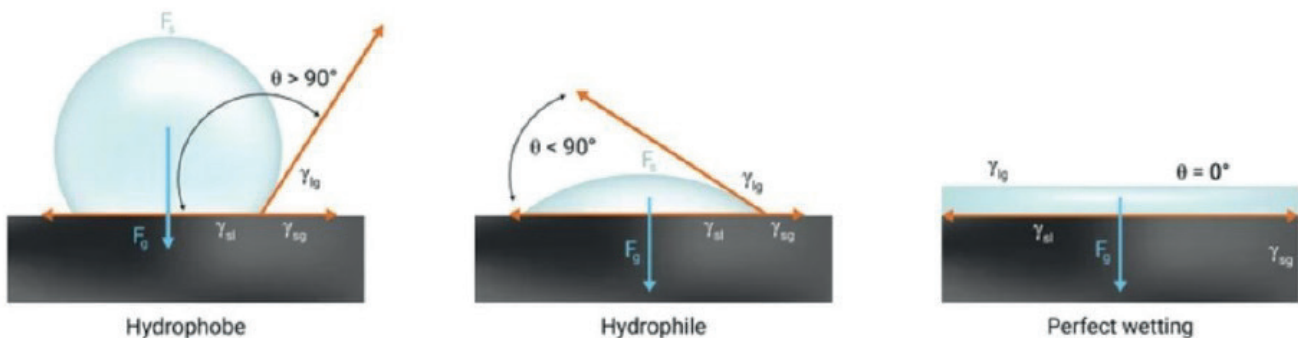


Figura 1: Rappresentazione grafica di superfici con diverso grado di bagnabilità.

The wettability of the implant was assessed by determining the surface contact angle according to the sessile drop method, using both double-distilled water (polar) and diiodomethane (apolar) as the liquid phase at room temperature ($\approx 8\mu\text{l}$ per drop). Eight measurements were taken, four with water and four with diiodomethane, using the Theta Lite Optical Tensiometer (Biolin Scientific, Stockholm, Sweden).

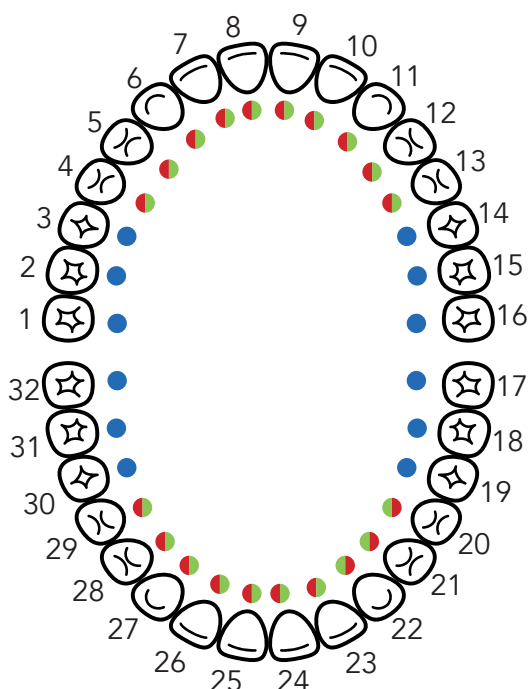
RESULTS:

All the samples showed a contact angle of less than 90° , and are therefore wettable by both a polar (water) and apolar (diiodomethane) solvent. However, the contact angle with diiodomethane appears slightly lower than that with water, indicating that the DFM 150-60 blasting gives the VARCAM001 sample a greater affinity for the lipophilic environment than the hydrophilic environment.

GENERAL INDICATIONS

For further information on each implant's indications and contraindications, see the relative instructions for use. The instructions for use are available at <https://www.iml.swiss/d/INSTRUCTION.pdf>

The UNIVERSE implants are offered in different diameters, with distinct functions for each:



Implants with a diameter of 2.9 are particularly thin implants that allow for the rehabilitation of individual missing teeth, such as:

- central incisors and lateral incisors of the upper arch, and even premolars under certain circumstances.
- central incisors and lateral incisors of the lower arch, and even premolars under certain circumstances.

(Indicated in red)

They can be applied in the situations listed above, and whenever there is little mesiodistal space and a reduced amount of vestibulo-lingual bone (the minimum distances to be observed in implant placement should be noted).

Implants with a diameter of 3.4 are best suited for rehabilitations in the premolar area, or in place of canines when there is insufficient bone thickness.

(Indicated in green)

Implants of even larger diameters (4.5 mm and 5.0 mm) are selected for molars and for all posterior sectors, both upper and lower.

(Indicated in blue)

The implant length should always be as long as possible, while respecting the noble structures (vascular and nerve), from which a safety distance of at least 2 mm must be kept.

The guided surgery, which allows better surgical planning, is a valuable aid.

PRE-OPERATIVE PLANNING

The implant surgery's success primarily depends on proper preoperative planning.

Knowing how to communicate correctly with the dental technician and the patient is essential for achieving the desired result.

The increasing availability of CONE BEAM CT and the development of interactive software applications capable of guiding the surgery towards a specific target with extreme precision have evolved considerably in the fields of both general and oral surgery.

Today, virtual dental implant planning allows for a prosthetically-guided approach that's capable of providing optimal prosthetic results in terms of design, aesthetics, occlusion, and loading. There are many software applications on the market that allow us to simulate and create surgical templates for surgery.

This approach has also changed the surgical paradigm, which prescribes the use of extended flaps to provide the surgeon with an optimal view of the surgical field. Today, "flapless" implant surgery, with or without immediate loading, has become more predictable.

Prior to surgery, the type of implant, diameter, and length are chosen, taking the anatomy and spatial circumstances (e.g. presence of included root remnants or angled teeth) into consideration.

The minimum distances between implants, teeth, and noble (vascular and nerve) structures should be observed in the design.

The position of the implant can be displayed in three dimensions:

- mesiodistal;
- vestibulo-lingual;
- coronoapical.

The implant prosthesis must always be axially loaded. The implant's placement must therefore take this factor into account. Any cantilever should be avoided, as it increases the risk of implant failure.

MESIODISTAL IMPLANT POSITION

The distances considered for the mesiodistal position of the implant start from the largest point of the implant itself: i.e. the coronal diameter. These measurements are crucial both when there are several implants placed close together and when there is just one implant placed next to a natural tooth.

For implant placement from the mesiodistal point of view, the following distances must be observed:

FIGURE 1: It is recommended to maintain a minimum distance of 1.5 mm from the perimeter of the implant to the adjacent tooth (mesial and distal).

FIGURE 2: It is recommended to maintain a minimum distance of 3mm between two adjacent implants (mesiodistal).

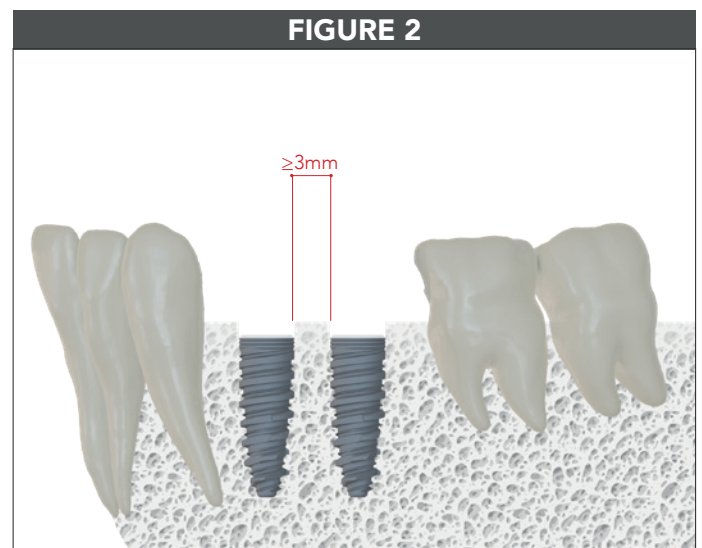
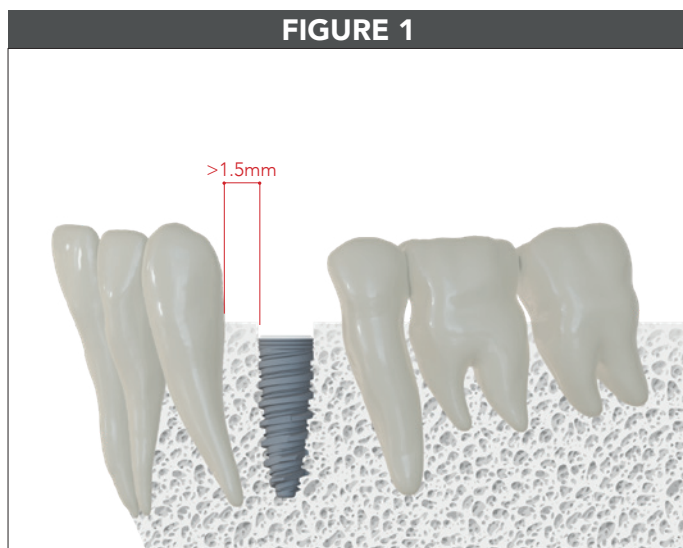
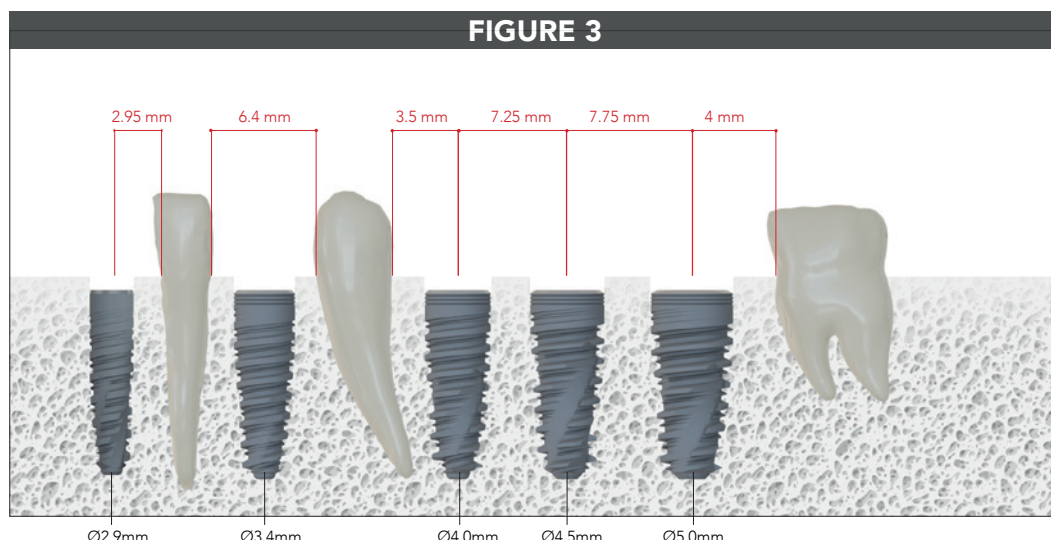


Figure 3 below illustrates a common situation of mixed implant placements with adjacent teeth. The measurements in millimetres are all taken from the bone surface of the tooth adjacent to the axial centre of the implant and between the implant centres.

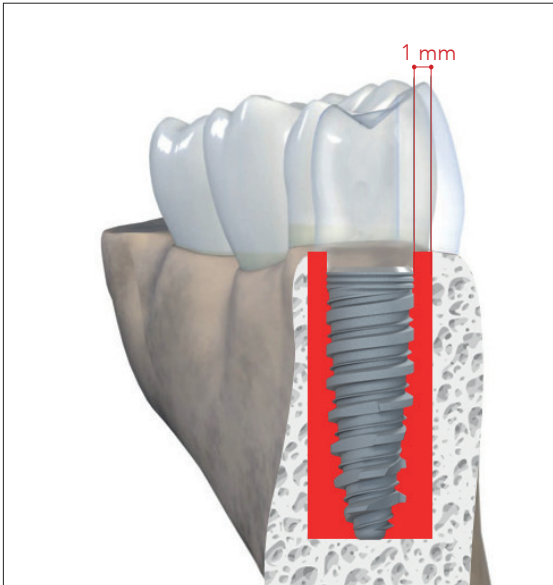
An effort should be made to maintain a minimum distance between implant perimeters of 3 mm in order to allow for better soft tissue healing and better home hygiene on the part of the patient.



VESTIBULO-LINGUAL IMPLANT POSITION

The placement of the implant must maintain at least 1 mm of bone on both the buccal and lingual or palatal surfaces.

If there is not at least 1 mm of vestibular or lingual bone, or if a bone surface on one of the four sides (mesial, distal, vestibular, or buccal) is missing, then bone regeneration surgery should be performed. The explanation of this procedure can be found in the specific texts on oral regenerative surgery, and it should only be carried out by experienced oral surgeons.



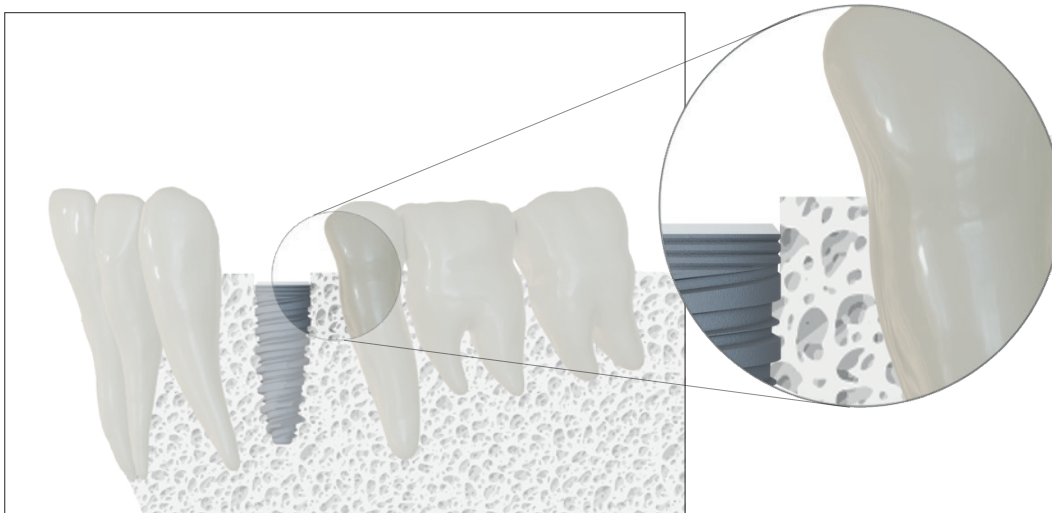
The bone layer must have a thickness of at least 1 mm.

Select the orofacial position and axis of the implant in such a way that the channel of the restoration screw inserted is behind the incisal edge.

APICAL-CORONAL IMPLANT POSITION

The implant can be placed subcrestal up to 1 mm below the crest of the bone, unless the practitioner carefully prepares the alveolus.

The placement of the implant from the apical-coronal point of view requires all of the implant's titanium threads to be submerged in the bone tissue. In aesthetic areas, especially the anterior sector, placement should be 3 mm below the gingival surface. This will ensure a better aesthetic outcome with the subsequent prosthesis.



GENERAL INDICATIONS FOR SURGICAL INSTRUMENTS

The surgical instruments for implant systems manufactured by IML SA are medical devices intended for temporary use within the oral cavity (continuous duration not exceeding 60 minutes), and can be reused after washing and sterilisation.

IML surgical instruments are used for the following purposes:

- preparation of the implant site;
- placement of the implant on site;
- tightening and unscrewing of all the connection screws (screw caps, healing screws, prosthetic screws, impression coping screws, etc.).

The surgical instruments are manufactured by IML according to the most stringent European and American standards, and are intended for use with dental implants manufactured by IML SA.

The use of the surgical instruments for procedures involving implants other than those manufactured by IML will limit the liability borne by IML and will void the product warranty.

The company shall bear no liability for the use of non-original equipment.

All IML SA surgical instruments are sold in NON-STERILE packaging.

They must be cleaned, disinfected, and sterilised prior to use in accordance with the instructions provided below.

Failure to comply with this warning could result in patient infections.

The materials used to manufacture the surgical instruments have been selected based on the properties indicated for their intended use, in accordance with EEC Directive 93/42 implemented in Italy by Law no. 46/97, Annex I Essential Requirements, point 7.1.

The relative code, content description, and batch number are indicated on each package.

These same data, which are also indicated on the labels inside the packaging, must always be cited by the doctor for any relevant communications.

In order to ensure protection against bacterial contamination, it is recommended to always use surgical gloves when handling the devices, both during use and during cleaning and sterilisation.

The failure to observe these rules could lead to cross-infection.

IML SA surgical drills are made from surgical steel with high resistance to corrosion and wear. They are intended for use with a contra-angle handpiece attachment, and must be used with a suitable micromotor. The surgical drills are externally irrigated, are manufactured either conical or cylindrical with a conical apex, and are DLC-coated.

The DLC (Diamond Like Carbon) coating, which gives the drill its characteristic black colour, not only improves the visibility of the depth markings during use, but also enhances performance:

- Increased cutting hardness, (precision)
- Increased abrasion resistance (number of uses)
- Increased resistance to chemical aggression. (Readability over time)

Their extremely accurate design and construction allow for vibration and oscillation-free operation. However, the incorrect insertion of instruments into the handpieces can lead to instrument vibration, eccentric rotation, premature wear, and bending of the shank. It is recommended to only utilise surgical micromotors suitable for the intended use. It is recommended to have the micromotors periodically checked by their manufacturers, in accordance with the manufacturers' instructions, in order to prevent any possible malfunctions (e.g. axis displacement of drive shafts, worn or malfunctioning grippers, etc.).

Failure to follow the instructions provided could lead to surgical complications and consequent health repercussions for the patient.

In order to avoid the development of bone necrosis, it is recommended to use the rotation speeds indicated on the following pages.

Lever-type movements increase the risk of instrument fracture, and should therefore be avoided. Sudden changes in speed should be avoided, and pressure must never be applied to forcibly stop the rotation of the instrument, as this could generate excessive heat in the tissues being cut, and could lead to premature

wear on the instrument and micromotor.

It is always recommended to work intermittently with an oscillating movement in a vertical direction, in order to avoid overheating and wear on the working part and excessive heat build-up in the alveoli being cut by the instrument.

The use of an appropriate liquid coolant is recommended.
Lack of adequate irrigation can lead to bone necrosis.

Drill wear is largely dependent on the type and density of the bone being milled: harder bone results in increased wear on the instruments.

It is important and necessary to check for drill wear every 20 uses, up to a maximum of 200.

The drills must never be resharpened prior to use. Never use damaged, bent or worn instruments.

UNIVERSE 2.9

Internal conometric
connection to double
staggered hexagon



iml⁺
swiss dental implants

UNIVERSE 2.9 IMPLANT SYSTEM AND EXTERNAL MORPHOLOGY



The perfect solution for:

- aesthetic position
- thin bone crest
- D1-D3 bone density
- limited space between front teeth
- immediate loading
- delayed loading



CONNECTION AND PROSTHETIC RANGE

In the tapered connection, a real "cold weld" is generated by the contact pressure between the surface of the implant's female cone and that of the abutment's male cone.

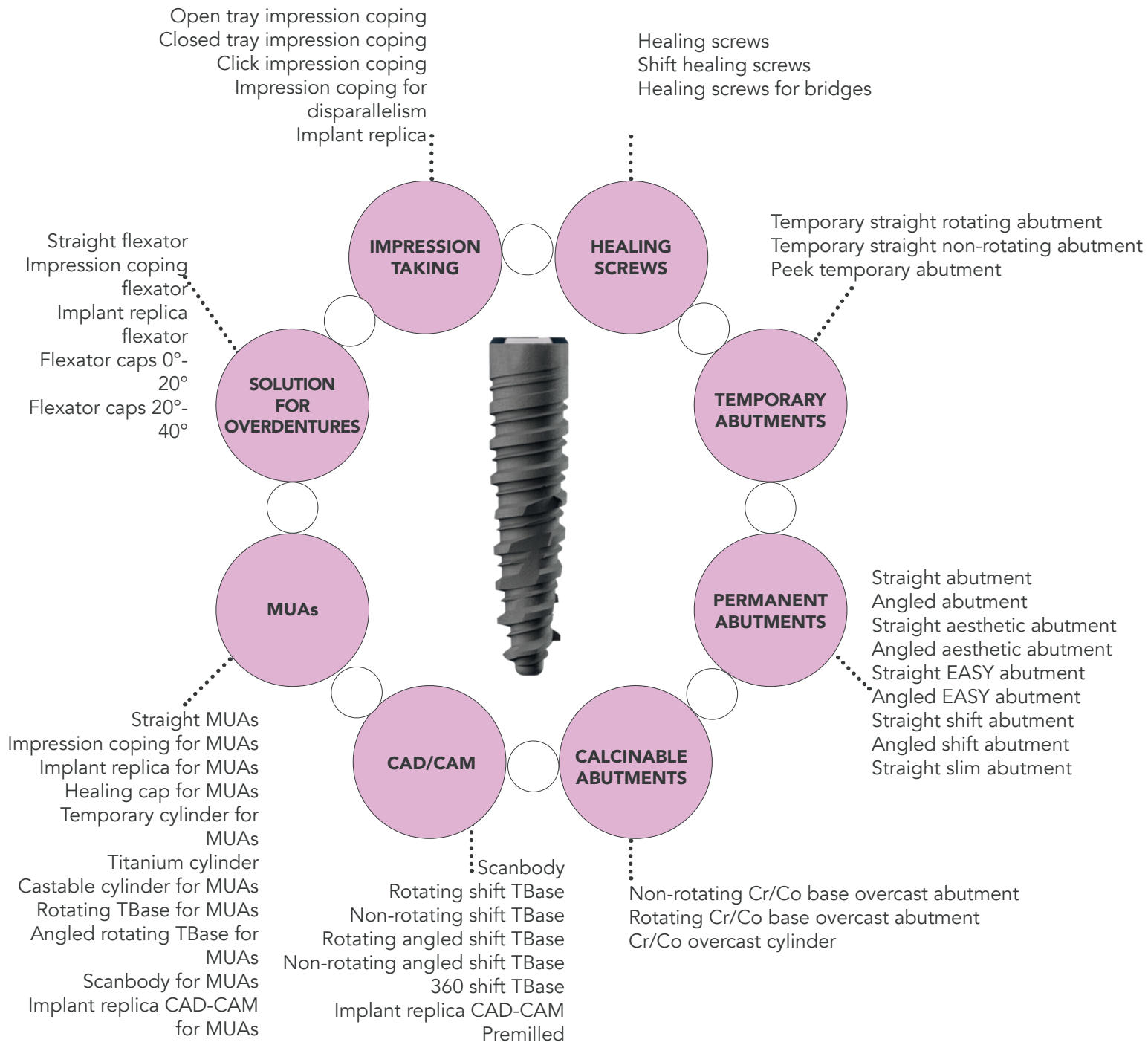
The friction created between two surfaces of equal taper, tightened to the recommended torque, is such that a direct, durable, and watertight joint is generated.

In fact, this type of connection is the only one that offers near ideal conditions for single-phase implants, which have been universally proven to be more durable than two-phase implants.

However, being able to mechanically achieve a perfect taper coupling requires special care and skill, right from the design phase.

IML's designers and engineers know how to measure and evaluate every critical point, in order to produce perfect components, in which the friction connection not only works according to design, but above all in the patient's mouth, and lasts for life.

The resulting system is effective and reliable, as proven by numerous studies conducted worldwide.



UNIVERSE 2.9 SYSTEM SURGICAL KIT

The UNIVERSE 2.9 implant system features a CD (cylindrical drilling) surgical protocol, which is used with the KIT-UN29 or the KITUN29-CD.

All the drills are made of high quality surgical steel and are vacuum heat-treated to ensure high resistance to wear and corrosion.

The drills are coated with a biocompatible DLC (Diamond Like Carbon) coating, are suitable for medical use due to their non-cytotoxic ceramic nature, and are UNI EN ISO 10993 certified (Biological evaluation of medical devices).

In contact with the human body, the DLC layer does not trigger rejection, does not cause damage, does not generate allergic reactions, and does not react with acidic and/or basic compounds.

The tribological characteristics of the treatment extend the life of instruments.

They provide antimicrobial properties, which help reduce bacterial growth and the risk of surgical infections. The chromaticity of the treatment and the white indentations ensure excellent visibility for the surgeon during the preparation of the implant site.

All the drills are attached to the contra-angle handpiece in accordance with ISO 1797-1 – Dentistry – Shanks for rotary instruments.

All the rotating tools (drills, countersinks, etc.) require external irrigation.

WARNINGS:

The kit contains retainers that allow the drills to be used safely, and are supplied separately. All the drills are marked with indicators referring to the height of the implant and the drill retainers.

Caution: the drill prepares the site with a depth 0.7 mm greater than the length of the implant.

The kit and the surgical instruments it contains are sold in NON-STERILE packaging.

They must be cleaned, disinfected, and sterilised prior to use.

Failure to comply with this warning could result in patient infections.

In order to ensure that the kit is always in good working order, it is recommended to check the wear status of the drills every 20 uses, up to a maximum of 200.

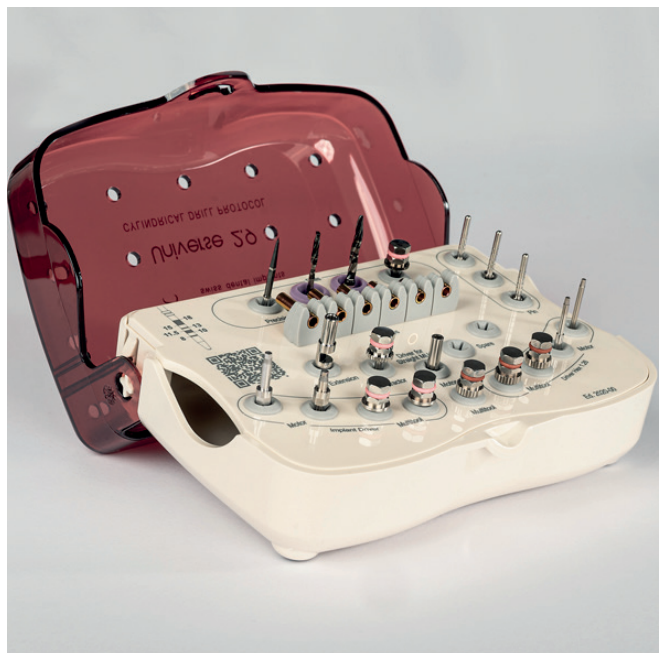
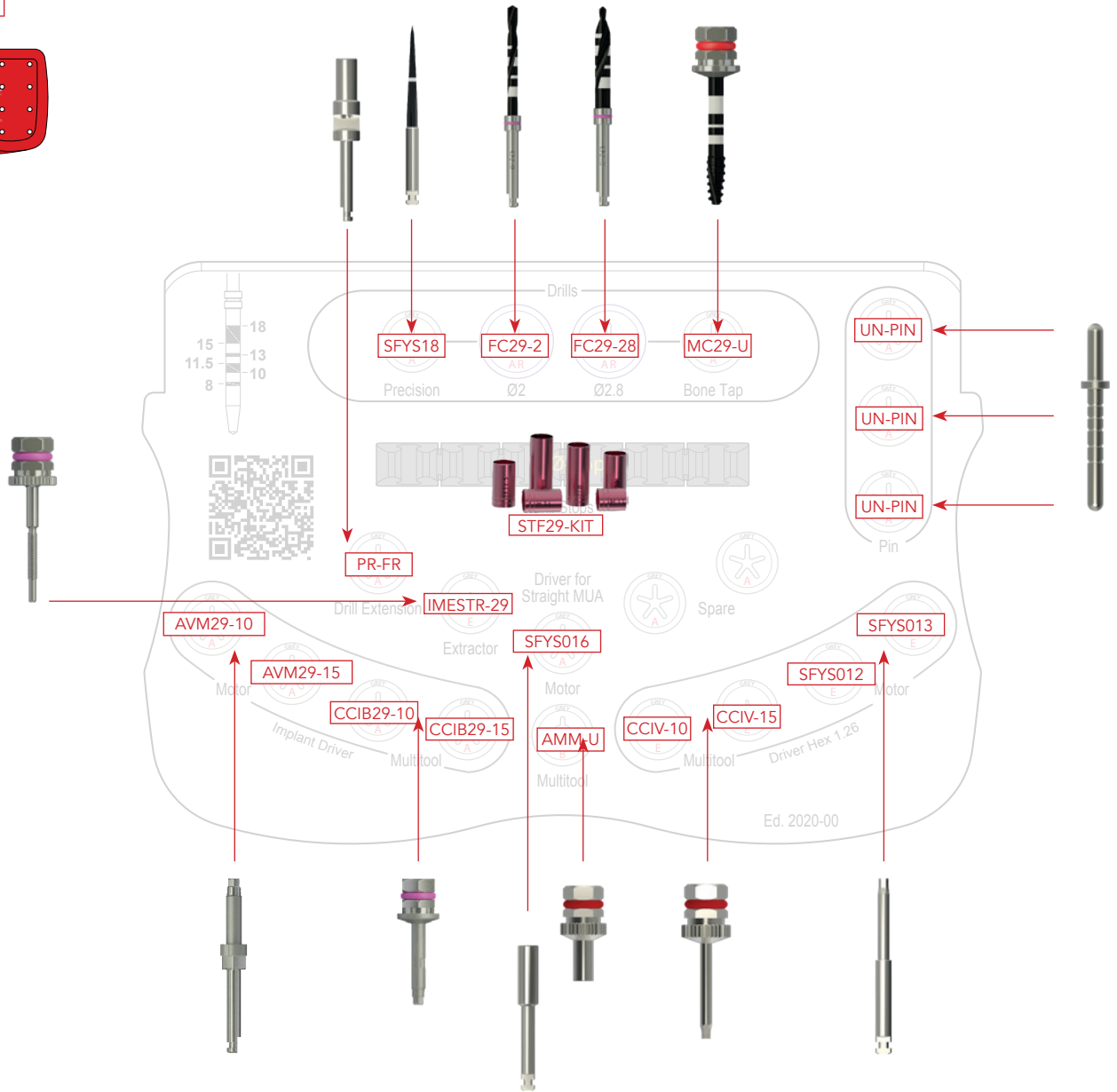
The lifespan of the drills depends on the type of bone processed each time they are used.

In order to preserve the instrument's service life, the surgeon must adhere to the international standards and, in particular, must follow the instructions contained in the chapter entitled "INSTRUMENT CLEANING AND MAINTENANCE".

For the rotation speed, follow the indications provided in the surgical protocols.

UNIVERSE 2.9 SURGICAL KIT

BOX-UN29



TOOL AND ACCESSORY DESCRIPTIONS



UNIVERSE 2.9 surgical instrument box

Made from autoclavable material, this box contains all the rotating and non-rotating surgical instruments needed to carry out the surgical and prosthetic protocols for the UNIVERSE 2.9 Line.

The figure of a drill with the various depth notch measurements is shown on the Kit.

A screen-printed QR code on the box provides a convenient link to the surgical protocol.

Supplied non-sterile



Precision drill

The precision drill serves to cut the cortical bone, and is therefore very sharp and pointed.

The design of the blades guarantees an effective cut at both the tip and the side. It has a maximum diameter of 2.0 mm and a laser marking positioned at 10 mm indicating the maximum depth to which the drill can be inserted. The precision drill is used to obtain a suitable guide hole for the subsequent drills.

The drill is made from surgical steel with a DLC surface treatment and a clear laser-etched reference notch.

Supplied non-sterile



UNIVERSE 2.9 cylindrical pilot drill Ø2

With its cylindrical shape and 2.00 mm diameter, the pilot drill is used to prepare the initial hole for the implant. The drill is easy to identify thanks to the diameter screen-printed on the shank of the drill itself.

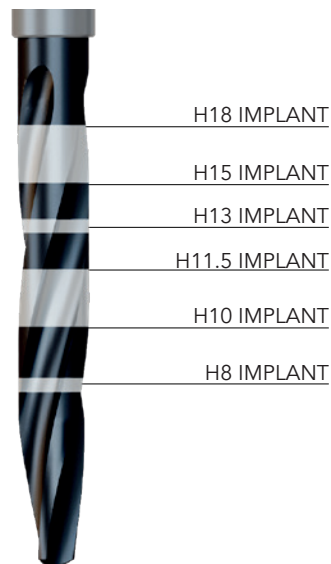
The drill features depth notches, and can be used in conjunction with fixed-depth stops.

It has laser-marked depth notches, and a helical shape with double-lead threads. It must be used with plenty of external irrigation.

The surgical drill is made from medical grade steel with a DLC (Diamond Like Carbon) coating, which gives the drill its characteristic black colour, and not only improves the visibility of the depth markings during use, but also enhances its mechanical performance and durability.

A coloured silicone O-ring is mounted on the drill, allowing the upper drill stops to stop in the correct position. The O-rings are pink as they identify the CC NP platform, and can be re-ordered when worn.

Caution: when drilling in the vicinity of vital anatomical structures, the increased length of the drill, which varies from drill to drill, must be taken into account.



Supplied non-sterile



UNIVERSE 2.9 cylindrical drill Ø2.8

Cylindrically shaped at Ø2.8 with a conical apex, the UNIVERSE 2.9 implant end drill is used to prepare the final hole for implant placement. The drill is easy to identify thanks to the diameter screen-printed on the shank of the drill itself.

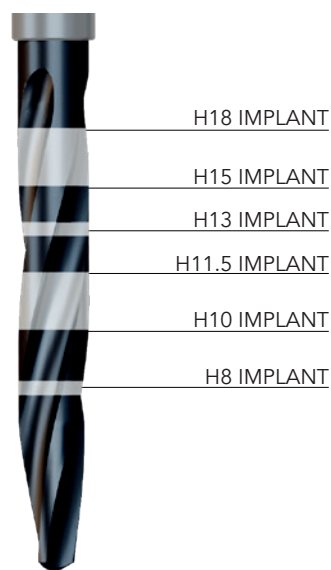
The drill features depth notches, and can be used in conjunction with fixed-depth stops.

It has laser-marked depth notches, and a helical shape with double-lead threads. It must be used with plenty of external irrigation.

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A coloured silicone O-ring is mounted on the drill, allowing the upper drill stops to stop in the correct position. The O-rings are pink as they identify the CC NP platform, and can be re-ordered when worn.

Caution: when drilling in the vicinity of vital anatomical structures, the increased length of the drill, which varies from drill to drill, must be taken into account.



Supplied non-sterile



UNIVERSE 2.9 kit drill stops for Ø2-2.8 cylindrical drills (6 pcs.)

The drill stops are devices that can be inserted onto IML drills designed to accommodate them, and are inserted over the tip of the drill itself. They allow the working length of a drill to be limited to a predetermined depth.

The drill stops have two notches, which serve as a reference when inserting them (the drill stops are inserted onto the drill from the side opposite the notches), and improve the grip when removing them from the drill.

All the drill stops have a colour-coding associated with the drill with which they are to be used, and each one has the depth of the associated implant laser-printed on it.

It is recommended to always check that the stop has been inserted to the desired depth. Incomplete insertion could reduce the depth of the preparation. Any insertion difficulties can be resolved by thoroughly cleaning both components.

It is also recommended to check the retention exerted by the stop, as too weak a retention force can cause the instrument to fall off the drill during the surgery. If the stops' retention capacity should decline, replacement O-rings can be ordered from IML SA. *Supplied non-sterile*



Drill extension

Manufactured in stainless steel. Allows the overall length of the drill to be increased.

Supplied non-sterile; must be autoclaved prior to use.

Supplied non-sterile



Guide pin

The parallelism pins can be used to check the placement axis of the implants and the parallelism between them.

The pins have a \varnothing 2.00 mm on both sides.

The standard IML parallelism pins have depth notches, which allow the height of the preparation to be controlled during the various steps.

As they are slightly smaller in diameter than the pin body, the notches are clearly visible on the intraoperative images.

The pin has two sides, one 7mm long and the other 15mm long, with notches from 6 to 13mm.

Supplied non-sterile



UNIVERSE 2.9 implant driver for motor

The UNIVERSE 2.9 implant does not require a carrier to be inserted into the implant site, as it is engaged directly in the connection by the dedicated implant drivers, which are specially designed to ensure a secure grip, not to deform the connection, and at the same time to allow for easy removal from the implant well.

The use of these drivers makes the surgical insertion procedure extremely simple.

The implant drivers are made of surgical steel, are subjected to stringent strength tests before being released onto the market, and feature a sandblasted area at the grip zone to improve the engagement grip.

The friction zone with the implant is designed and positioned in a different zone than where the conometry of the prosthetic parts will act.

The instruments have a reference notch indicating the driver's correct insertion position.

With a simple push, the conometry is activated and the system can be safely withdrawn.

The implant drivers offer the possibility of orienting the hexagonal connection as desired, since they have a hexagonal index corresponding to the prosthetic index and the lines engraved on the component.

When using the Implant drivers, care should be taken to maintain the working axis as perpendicular as possible. It is also essential to avoid abrupt and uneven movements.

Failure to observe these usage precautions and exceeding the insertion torque could result in instrument failure.

Supplied non-sterile



UNIVERSE 2.9 Multitool Implant driver

As described for the motor mount implant drivers, the UNIVERSE 2.9 implant does not require a carrier to be inserted into the implant site, as it is engaged directly in the connection by the dedicated implant drivers. The use of these drivers makes the surgical insertion procedure extremely simple.

The multitool implant drivers are made of surgical steel, are subjected to stringent strength tests before being released onto the market, and feature a sandblasted area at the grip zone to improve the engagement grip.

The friction zone with the implant is designed and positioned in a different zone than where the conometry of the prosthetic parts will act.

The instruments have a reference notch indicating the driver's correct insertion position.

With a simple push, the conometry is activated and the system can be safely withdrawn.

The implant drivers offer the possibility of orienting the hexagonal connection as desired, since they have a hexagonal index corresponding to the prosthetic index and the lines engraved on the component.

The multitool implant drivers have a colour-coded O-ring to indicate the relative platform of use (pink O-ring IML CC NP).

When using the Implant drivers, care should be taken to maintain the working axis as perpendicular as possible.

It is essential to use a slow and even movement with the ratchet when tightening, avoiding abrupt movements as much as possible. Failure to observe these usage precautions and exceeding the insertion torque could result in instrument failure.

In order to ensure greater stability during tightening, it is recommended to maintain light and constant pressure on the end inserted in the torque ratchet with one finger.

Supplied non-sterile



Dynamometric ratchet

Supplied non-sterile



Fixed ratchet

Supplied non-sterile



Digital adapter for multitool drivers

Made from grade 5 medical titanium, this adapter allows instruments with multitool (ratchet) connections to be used manually.

Supplied non-sterile



Multitool driver for screws

All the screw drivers are made of electropolished and hardened surgical steel, and the design of the part connecting the driver to the screws is designed to engage a screw with a 1.26mm internal hexagonal connection.

The slightly conical coupling between the driver and screw allows for adequate retention of the latter within the oral cavity.

It is important to check regularly that this functionality has not been lost due to wear and tear, otherwise the unit should be replaced.

The upper knurled area also allows the driver to be used digitally.

The drivers are available with shanks of different lengths in order to facilitate ergonomics based on the patient's anatomy.

Important warning

Excessive torque can strip the shafts of the clamping screws and round off the corners of the screwdrivers, causing potentially serious intraoperative or prosthetic complications.

The recommended torques for tightening the various components must be scrupulously respected, without ever exceeding 35 Ncm.

Lever-type movements should be avoided, as they increase the risk of fracture.

Make sure that the hexagonal profile of the driver tip has been properly inserted into the hexagon of the screws to be tightened before tightening.

Incorrect insertion can lead cause the hexagon of the screwdriver or the screw to be stripped.

The drivers have a slightly conical profile, which ensures that the hexagon of the driver fits inside the hexagon on the screw heads, so that the screw can be brought safely into the mouth without getting lost inside the oral cavity.

Supplied non-sterile



UNIVERSE 2.9 Motor driver for screw

All the screw drivers are made of electropolished and hardened surgical steel, and the design of the part connecting the driver to the screws is designed to engage a screw with a 1.26mm internal hexagonal connection.

The slightly conical coupling between the driver and screw allows for adequate retention of the latter within the oral cavity.

It is important to check regularly that this functionality has not been lost due to wear and tear, otherwise the unit should be replaced.

The micromotor mount drivers are made from surgical steel, and are compliant with the contra-angle handpiece compatibility standard (ISO 1797-1).

The drivers are intended exclusively for use with micromotors, and are available with shanks of different lengths in order to facilitate ergonomics based on the patient's anatomy.

Important warning

Excessive torque can strip the shafts of the clamping screws and round off the corners of the screwdrivers, causing potentially serious intraoperative or prosthetic complications.

The recommended torques for tightening the various components must be scrupulously respected, without ever exceeding 35 Ncm.

Lever-type movements should be avoided, as they increase the risk of fracture.

Make sure that the hexagonal profile of the driver tip has been properly inserted into the hexagon of the screws to be tightened before tightening.

Incorrect insertion can lead cause the hexagon of the screwdriver or the screw to be stripped.

The drivers have a slightly conical profile, which ensures that the hexagon of the driver fits inside the hexagon on the screw heads, so that the screw can be brought safely into the mouth without getting lost inside the oral cavity.

Supplied non-sterile



UNIVERSE 2.9 multitool remover for abutments

The engagement of the prosthetic components in the implant with IML Conical Connections results in a firm and stable coupling, which ensures the proper sealing of the implant and stability for the prosthesis.

The final coupling can be removed with a dedicated manual extractor. The pink O-ring identifies instruments suitable for the DC NP connection (M1.6 thread)

The upper knurled area also allows the driver to be used digitally.

Supplied non-sterile



Multitool driver for straight MUAs

This mounting driver for MUAs can be used directly on the ratchet, and is used to permanently apply straight MUA abutments.

The upper knurled area also allows the driver to be used digitally.

Important warning:

Excessive torques can strip the hexagonal wrench for the abutments.

The recommended torques for tightening the various components must be scrupulously respected, without ever exceeding 35 Ncm.

Supplied non-sterile



Motor driver for straight MUAs

This mounting driver for MUAs can be used directly on the micromotor, and is used to permanently apply straight MUA abutments.

The micromotor mount drivers are made from surgical steel, and are compliant with the contra-angle handpiece compatibility standard (ISO 1797-1).

Important warning

Excessive torques can strip the hexagonal wrench for the abutments.

The recommended torques for tightening the various components must be scrupulously respected, without ever exceeding 35 Ncm.

Supplied non-sterile



UNIVERSE threadformer

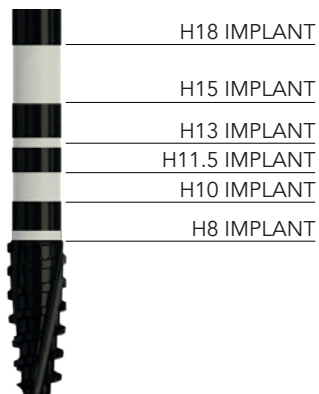
The threadformer is made of medical steel, and can be used manually with either the digital adapter or the ratchet.

They are mainly used in the presence of compact bone to prevent implant placement from being carried out in a forced manner and causing compressive stress in the bone, thus compromising healing

UNIVERSE implants are easy-to-insert self-tapping implants with an excellent cutting capacity; however, the use of the threadformer is recommended in all cases where the type of bone requires it, in order to facilitate the fixture's insertion.

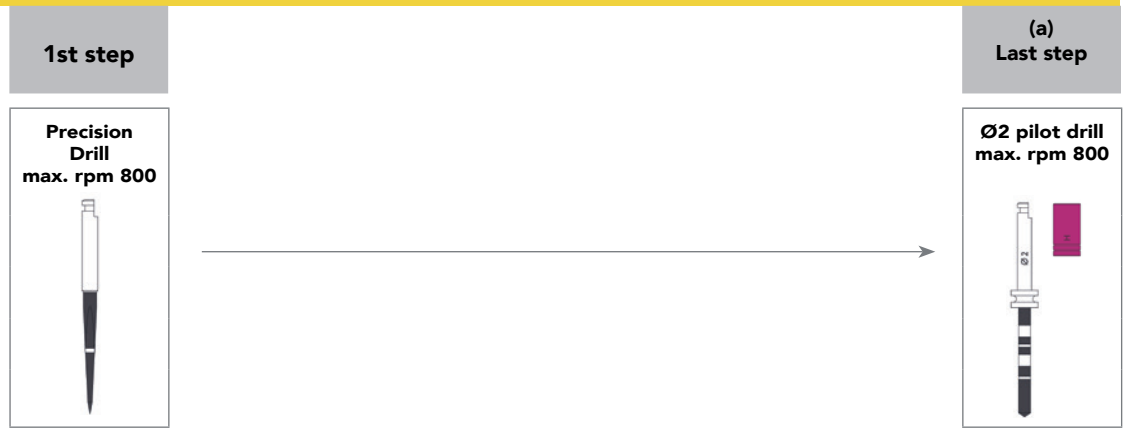
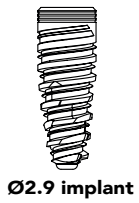
They are DLC-coated and have laser-printed reference notches.

The pink O-ring in the ratchet connection identifies instruments suitable for the DC NP connection. *Supplied non-sterile*

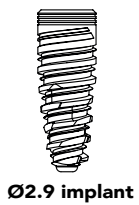


D4

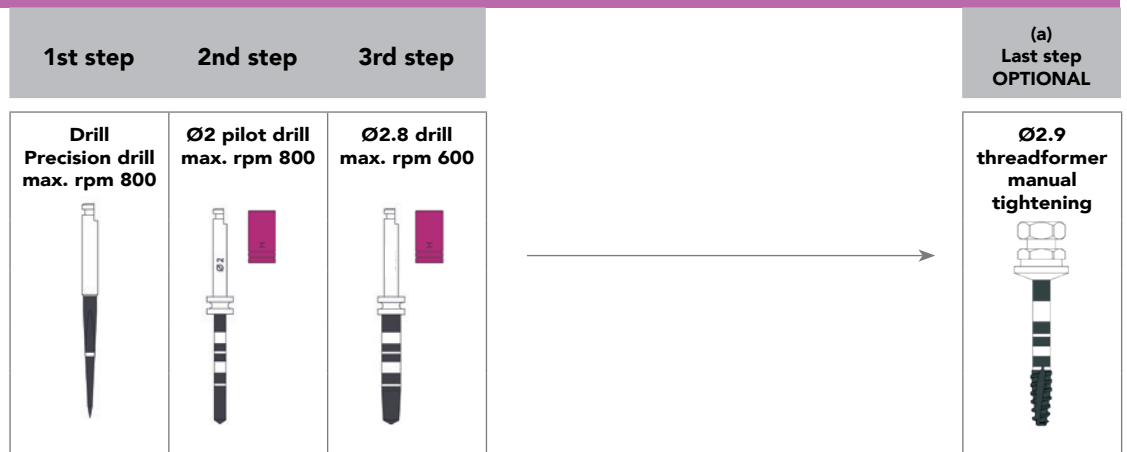
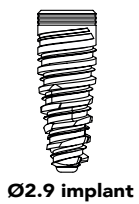
GENERAL OUTLINE OF THE UNIVERSE 2.9 SURGICAL PROTOCOL



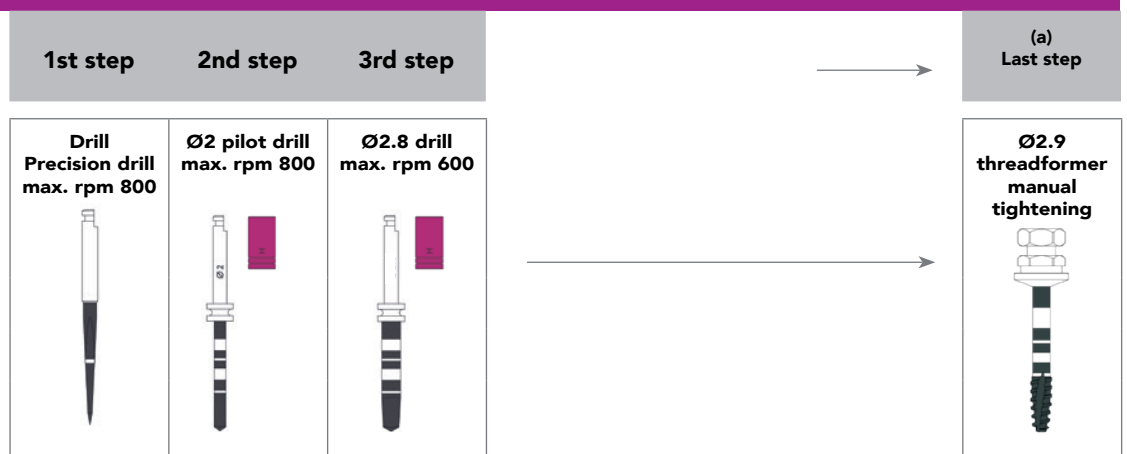
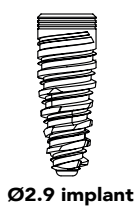
D3

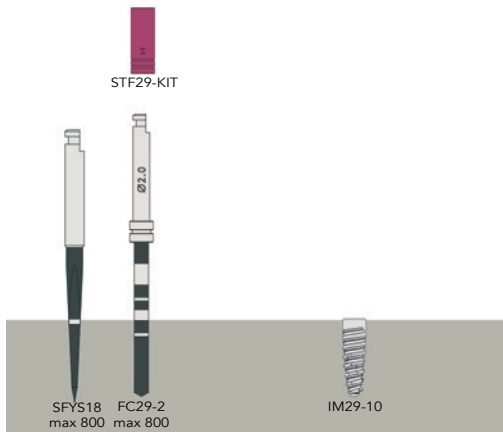


D2



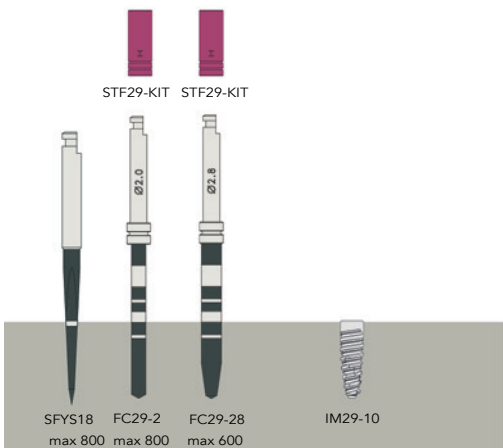
D1



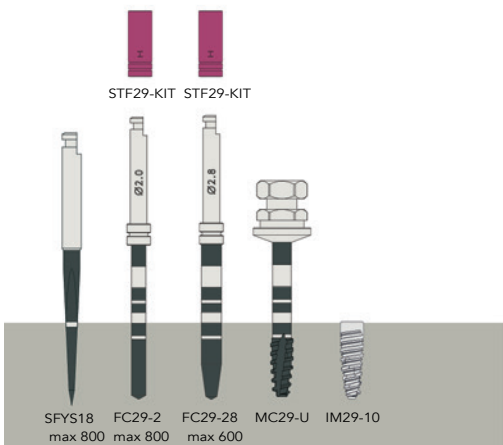


NOTE: Maximum recommended torque: 35 Ncm

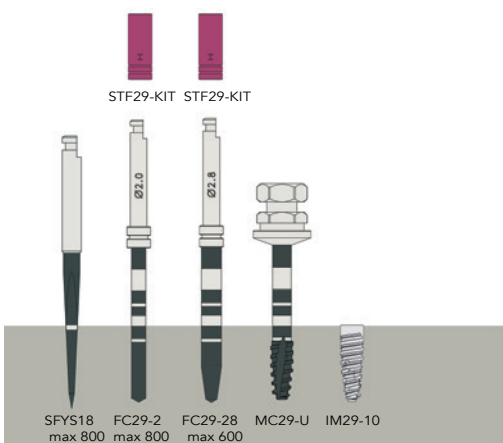
- SFYS18 Fresa lanceolata Precision drill
- STF29-KIT Bussola stop Drill stop
- FC29-2 Fresa pilota cilindrica Ø2 Cylindrical pilot drill Ø2
- IM29-10 Impianto Ø2.9 - h10 Implant Ø2.9 - h10



- SFYS18 Fresa lanceolata Precision drill
- STF29-KIT Bussola stop Drill stop
- FC29-2 Fresa pilota cilindrica Ø2 Cylindrical pilot drill Ø2
- FC29-28 Fresa cilindrica Ø2.8 Cylindrical drill Ø2.8
- IM29-10 Impianto Ø2.9 - h10 Implant Ø2.9 - h10



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- MC29-U Maschiatore Threadformer
- IM29-10 Impianto Ø2.9 - h10 Implant Ø2.9 - h10



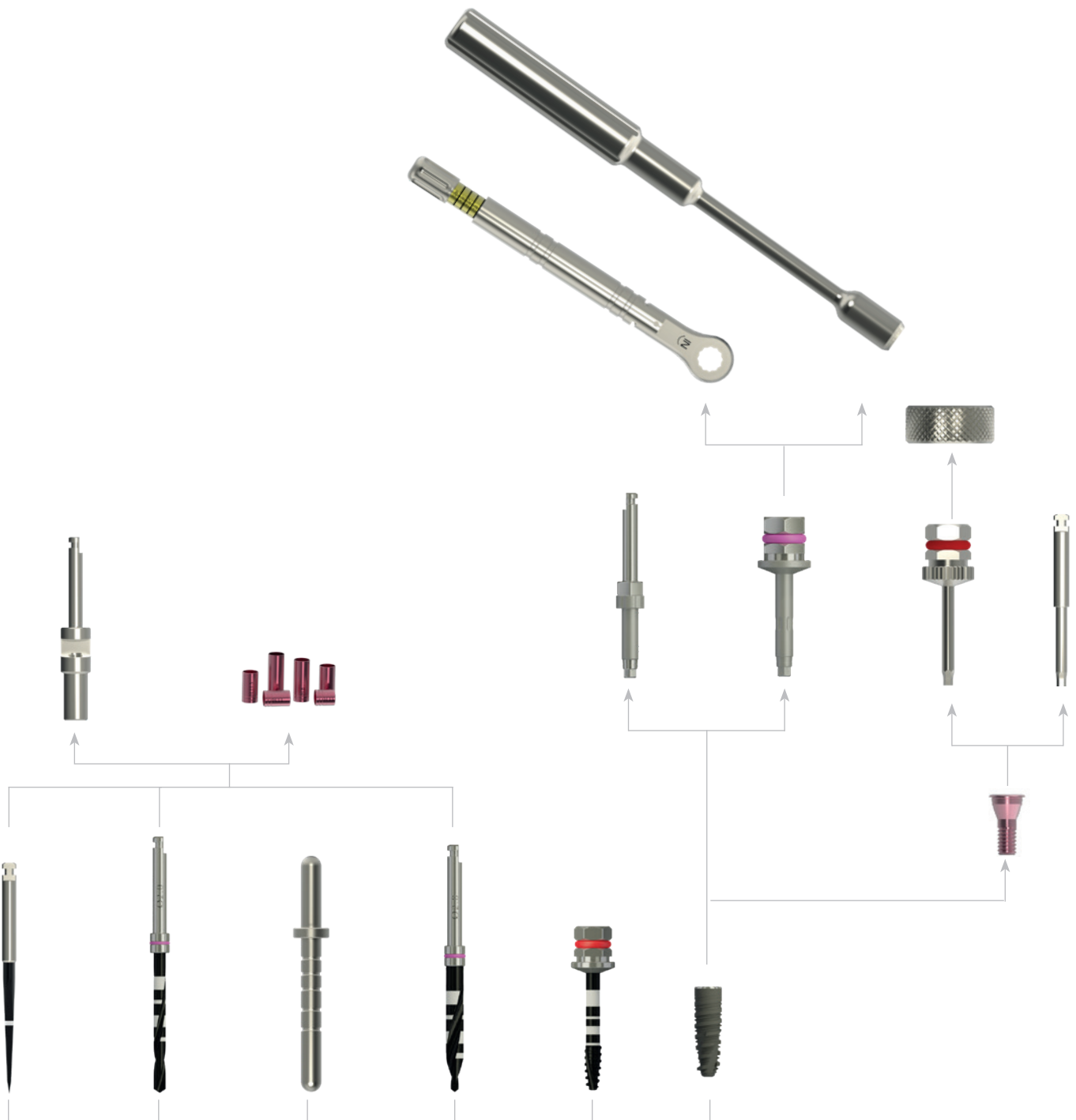
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- MC29-U Maschiatore Threadformer
- IM29-10 Impianto Ø2.9 - h10 Implant Ø2.9 - h10

UNIVERSE 2.9 IMPLANT BED PREPARATION

After opening the flap, the preparation of the implant site begins with a precision drill, which serves to cut the cortical bone and create the opening for the subsequent use of the pilot drill, ensuring a quick and precise cut (step 1).

The pilot drill and the cylindrical drill (steps 2 to 3) are utilised, depending on the surgical protocol to be followed, based on the type of bone present.

It is advisable to use the threadformer when the torque exceeds 35 Ncm.



INSTRUCTIONS



Fig.1

STEP 1: This consists of determining the precise implant insertion point. In the case of a very thin alveolar ridge, it is recommended to flatten it carefully using, for example, a round or flame bur mounted on a turbine (used transversely), in order to obtain a flat bone surface. Immediately afterwards, the precise implant preparation point can be marked with a $\text{Ø}1.4$ mm round bur. This last step cannot be carried out in the case of post-extraction implant placement. (Fig.1 and 2)

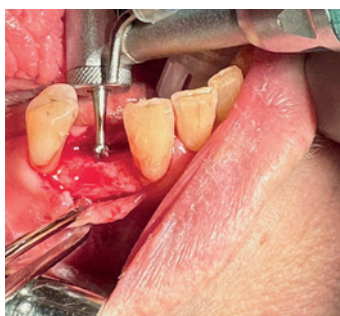


Fig.2

STEP 2: Use the precision drill to cut the cortical bone and create the opening for the subsequent use of the pilot drill. This can also be used in the absence of a flat or even surface. (Fig.3)

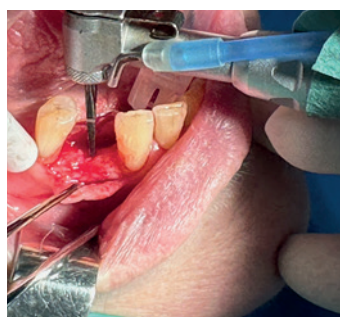


Fig.3

STEP 3: during this step, the depth of the implant preparation and its respective axis are determined. The $\text{Ø} 2$ mm pilot drill is used, drilling to a depth of about 6 mm. The direction of the preparation is checked with a parallelism pin. The pilot drill is then used to drill to the final preparation depth. It may be useful to check the preparation axis and depth several times with the parallelism pin. It is recommended to perform an endoral X-ray with the pin inserted into the implant site to compare the preparation with the neighbouring anatomical structures. (Fig.4)



Fig.4

STEP 4: enlarge the implant site to the previously determined depth with the $\text{Ø} 2.8$ mm drill. Pay close attention to the vascular and nerve structures near the implant site during this stage (the stop drill stops in the IML kit are useful). (Fig.4)

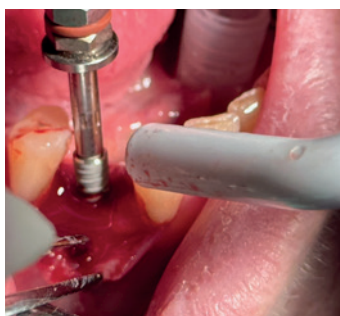


Fig.5

STEP 5: not always necessary. This step consists of shaping the most superficial part of the implant site with a threadformer. It is performed when the patient's autologous bone is particularly hard and compact. For example in the mandible with D1 bone. With subsequent placement of the dental implant in situ. (Fig.5)

IMPLANT EXTRACTION PROCEDURE



- Check the packaging for the implant's description, length, diameter, and sterilisation expiry date.

If the packaging or tamper-evident seal is damaged, its contents may no longer be sterile, and the product should therefore not be utilised.

Open the package and take out the transparent grey polypropylene (PP) container, closed with a white polypropylene (PP) cap with a security seal, and the adhesive labels bearing the implant identification code and lot number, one of which can be placed on the doctor's medical chart and the other on the patient's implant passport.



- Opening the container:

the practitioner unscrews the white polypropylene (PP) cap with safety seal, thus exposing the grey ABS container containing the implant and the red ABS container containing the screw cap. The dental implants are positioned between two titanium spacers.



- Set the torque value on the torque ratchet or micromotor (max. speed 25 rpm) to 45 Ncm for UNIVERSE implants and 35 Ncm for UNIVERSE 2.9 implants.



- Mount the multitool implant driver on the ratchet or the motor mount implant driver on the handpiece.



- After having checked the product's description on the label, the practitioner can extract the container containing the implant.



- The practitioner extracts the red plug containing the screw cap, placing it on a sterile towel so that it will only be handled by the practitioner while wearing sterile gloves from that point onward.



- Insert the multitool implant driver or motor mount implant driver into the implant's connection, taking care to engage the hexagon correctly: the sandblasted portion should be inserted all the way to the reference notch.



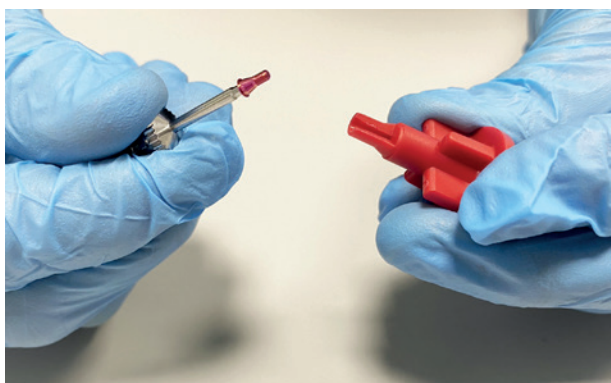
- Pull the implant out of the implant retainer by pressing on the ends of the grey element ("spring action").

IMPLANT PLACEMENT

Start screwing the implant into the bone, so that the implant is immersed in the bone, leaving only the switching platform exposed. When inserting the implant, it is recommended to try to maintain a biological width of 4 mm from the end of the mucosa. (Scientific publication by Dr. Diego Lops)



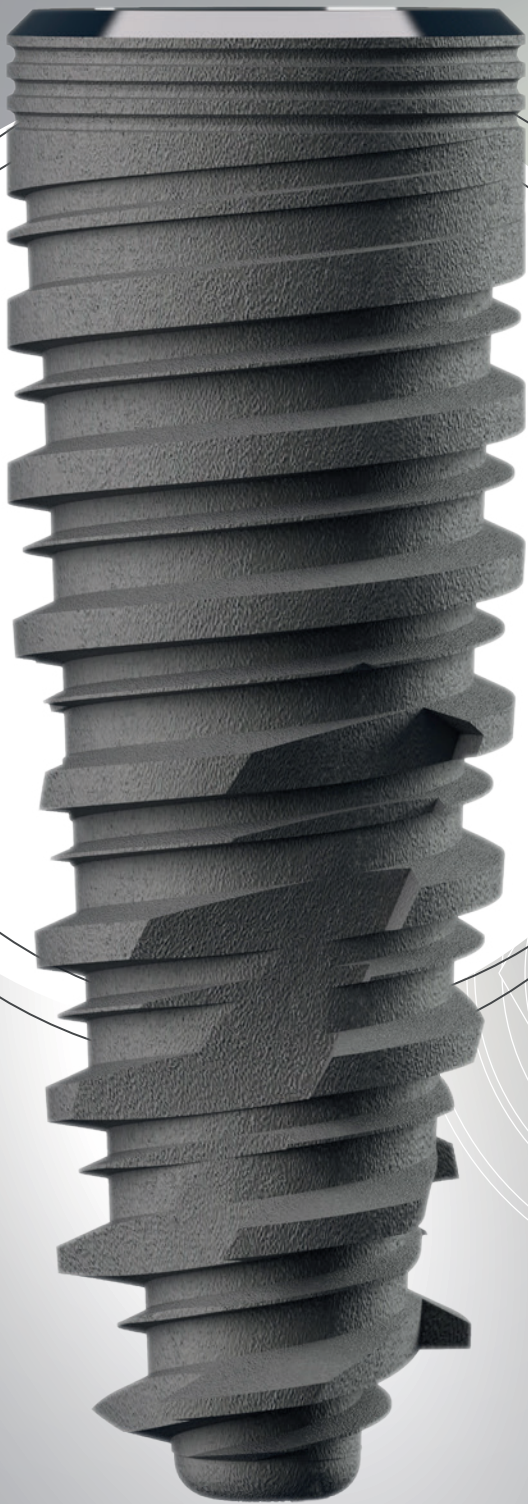
PROCEDURE FOR COVER SCREW EXTRACTION AND PLACEMENT



- Remove the cover screw from the red ABS container and manually screw it onto the placed implant.

UNIVERSE

Internal conometric
connection to double
staggered hexagon



iml⁺
swiss dental implants

The perfect solution for:

- low density bone
- post-extraction
- deferred loading
- immediate loading



CONNECTION AND PROSTHETIC RANGE

In the cone connection, a real “cold weld” is generated by the contact pressure between the surface of the implant’s female cone and that of the abutment’s male cone.

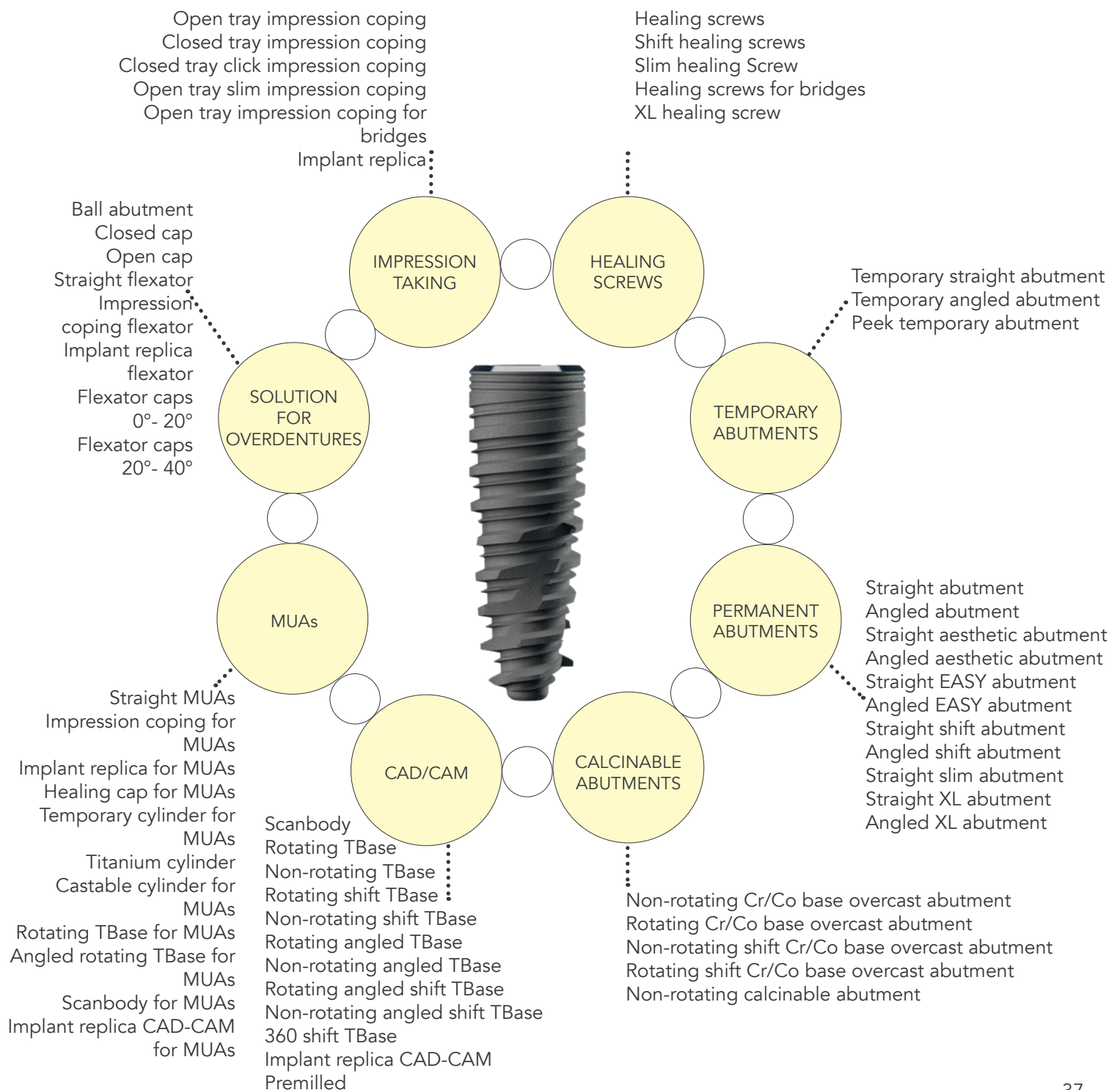
The friction created between two surfaces of equal taper, tightened to the recommended torque, is such that a direct, durable, and watertight joint is generated.

In fact, this type of connection is the only one that offers near ideal conditions for single-phase implants, which have been universally proven to be more durable than two-phase implants.

However, being able to mechanically achieve a perfect taper coupling requires special care and skill, right from the design phase.

IML’s designers and engineers know how to measure and evaluate every critical point, in order to produce perfect components, in which the friction connection not only works according to design, but above all in the patient’s mouth, and lasts for life.

The resulting system is effective and reliable, as proven by numerous studies conducted worldwide.



UNIVERSE SYSTEM SURGICAL KIT

The UNIVERSE implant system has two different surgical protocols: CD (Cylindrical Drilling) and TD (Tapered Drilling). The CD protocol is applied using the KIT-UNCD, and is a standard protocol, while the TD protocol uses the KIT-UNTD allows for implant placement with the simple passage of two drills, for saving considerable time for the operator.

The UNIVERSE 2.9 system's arrival on the market was accompanied by a complete kit, which can be used for both the UNIVERSE and UNIVERSE 2.9 implant systems.

All the drills are made of high quality surgical steel and are vacuum heat-treated to ensure high resistance to wear and corrosion.

The drills are coated with a biocompatible DLC (Diamond Like Carbon) coating, are suitable for medical use due to their non-cytotoxic ceramic nature, and are UNI EN ISO 10993 certified (Biological evaluation of medical devices).

In contact with the human body, the DLC layer does not trigger rejection, does not cause damage, does not generate allergic reactions, and does not react with acidic and/or basic compounds.

The tribological characteristics of the treatment extend the life of instruments.

They provide antimicrobial properties, which help reduce bacterial growth and the risk of surgical infections. The chromaticity of the treatment and the white indentations ensure excellent visibility for the surgeon during the preparation of the implant site.

All the drills are attached to the contra-angle handpiece in accordance with ISO 1797-1 – Dentistry – Shanks for rotary instruments.

All the rotating tools (drills, countersinks, etc.) require external irrigation.

WARNINGS:

The stop drill stops for the cylindrical drills are supplied in 2 separate kits, to be used based on the diameter of the drill, indicated by the colour coding, which is present on the anodised drill stops and on the drills, whose coloured o-rings allow for immediate identification.

In particular:

RED BUSHING KIT: for use with the drills with red o-rings: Ø 2, 2.7, 3.1, 3.6, and 4;

GREEN BUSHING KIT: for use with the drills with green o-rings: Ø 4.4 and 5.3.

The drills are marked with notches, which refer to the height of the implants and the stop drill stops.

Caution: the drill prepares the site with a depth 0.7 mm greater than the length of the implant.

In order to ensure that the kit is always in good working order, it is recommended to check the wear status of the drills every 20 uses, up to a maximum of 200.

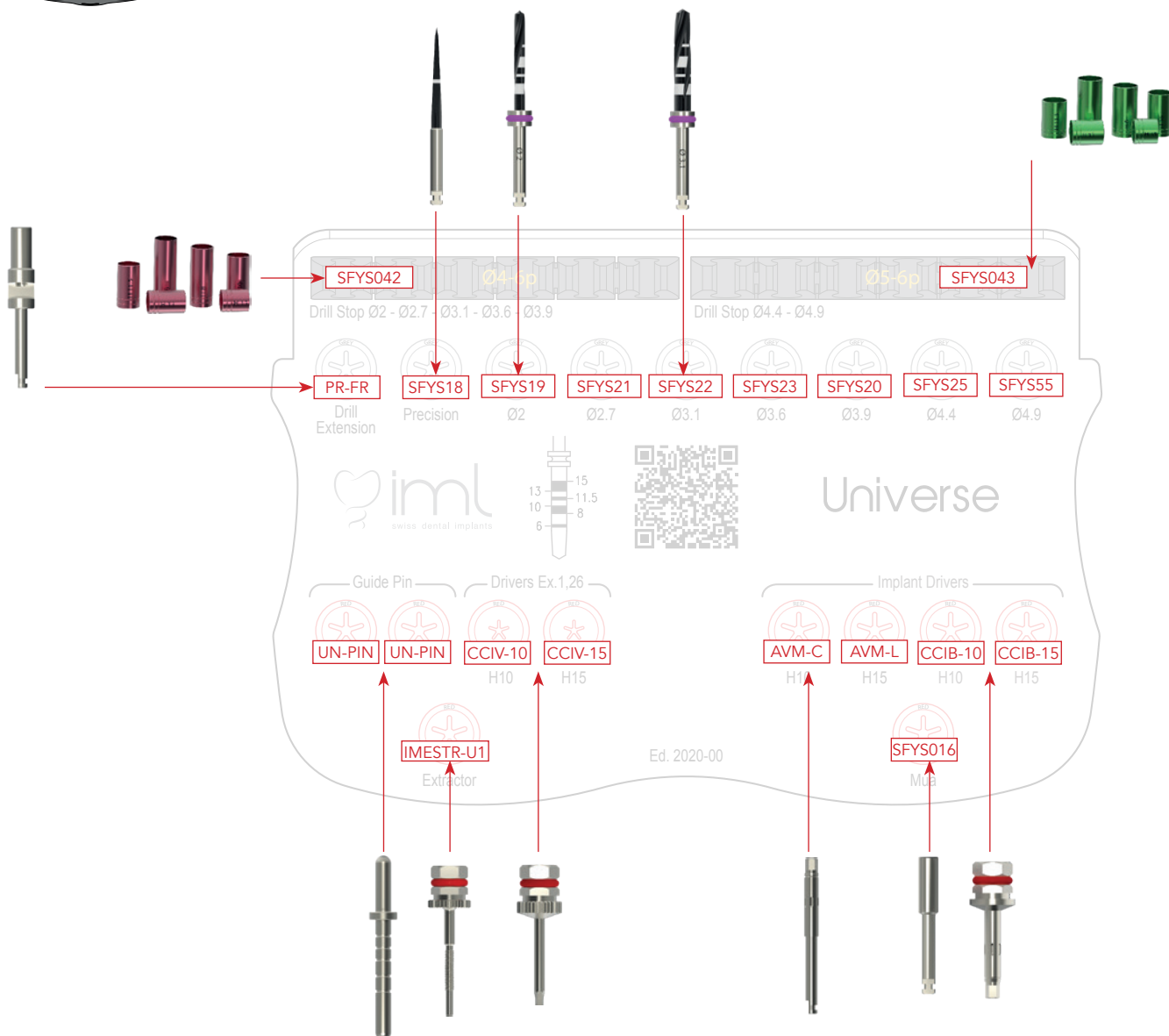
The lifespan of the drills depends on the type of bone processed each time they are used.

In order to preserve the instrument's service life, the surgeon must adhere to the international standards and, in particular, must follow the instructions contained in the chapter entitled "INSTRUMENT CLEANING AND MAINTENANCE".

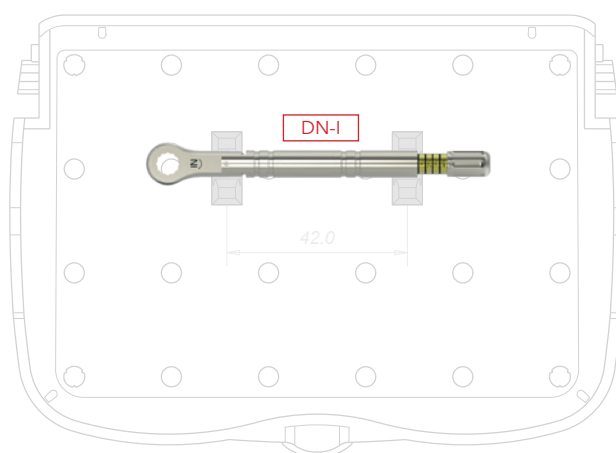
For the rotation speed, follow the indications provided in the surgical protocols.

UNIVERSE CD SURGICAL KIT

BOX-UNCD

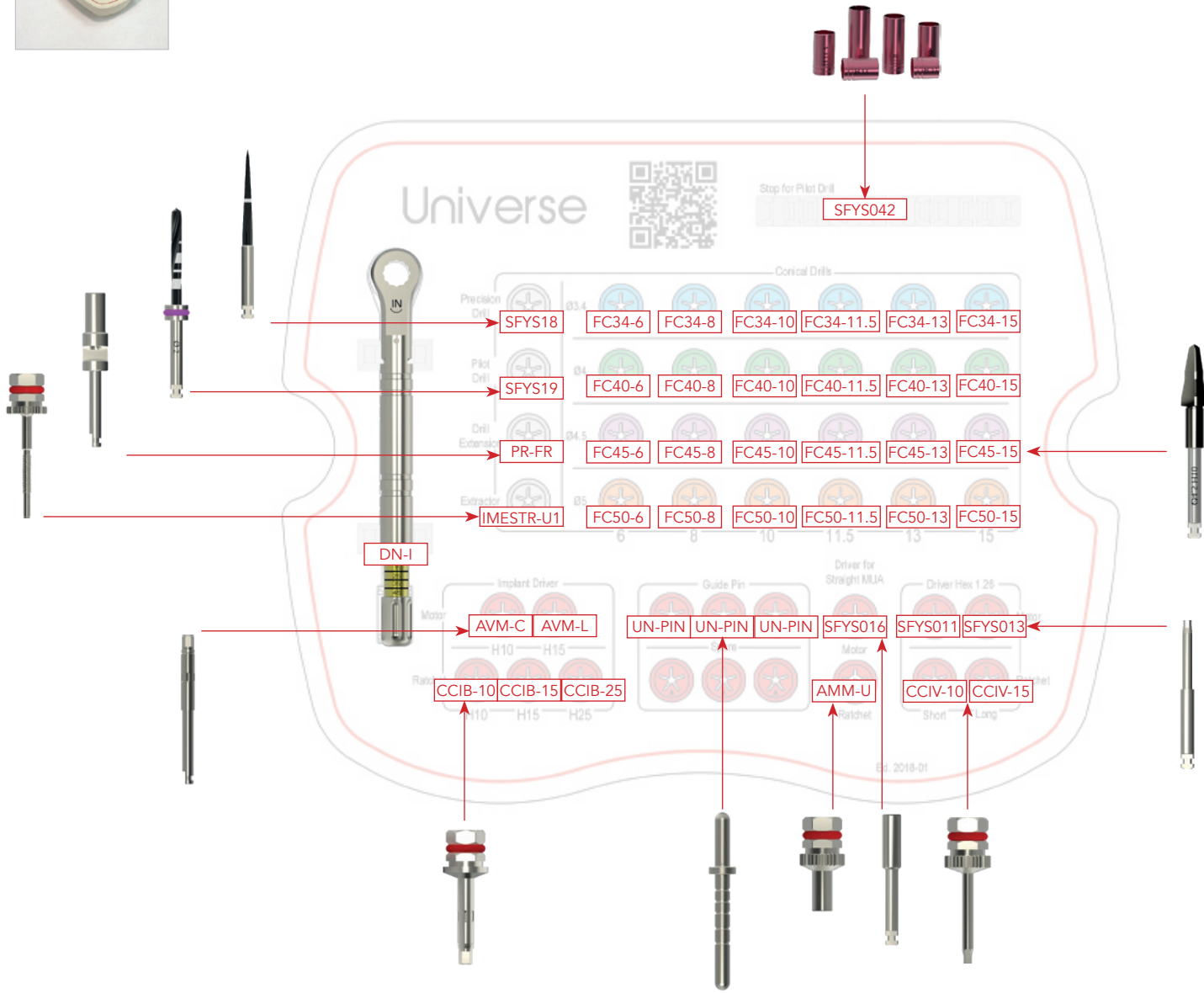


LOWER TRAY

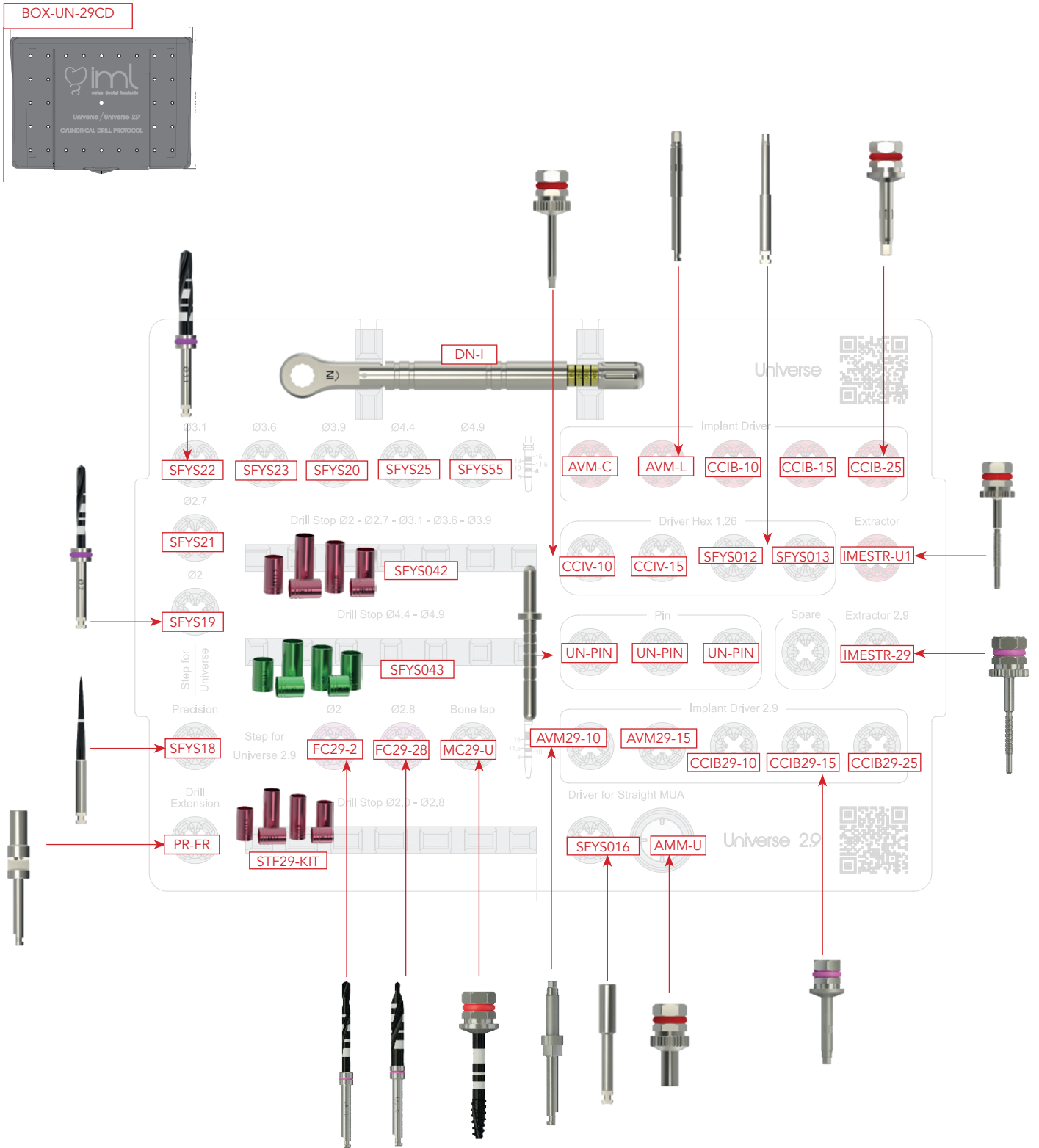


UNIVERSE TD SURGICAL KIT

BOX-UNTD



UNIVERSE UN29-CD SURGICAL KIT





CYLINDRICAL DRILL PROTOCOL
UNIVERSAL UNIVERSAL

SWISS QUALITY

Ø3.2

Ø2.1

Ø2

Ø2.8

Step for Precision

Step for Universal

Drill Extension

TOOL AND ACCESSORY DESCRIPTIONS



UNIVERSE CD box for surgical instruments

Made from autoclavable material, this box contains all the rotating and non-rotating surgical instruments needed to carry out the surgical and prosthetic protocols for the UNIVERSE Line.

The figure of a drill with the various depth notch measurements is shown on the Kit.

A screen-printed QR code on the box provides a convenient link to the surgical protocol.

Supplied non-sterile



UNIVERSE TD box for surgical instruments

Made from autoclavable material, this box contains all the rotating and non-rotating surgical instruments needed to carry out the surgical and prosthetic protocols for the UNIVERSE Line.

The figure of a drill with the various depth notch measurements is shown on the Kit.

A screen-printed QR code on the box provides a convenient link to the surgical protocol.

Supplied non-sterile



UNIVERSE 2.9 and UNIVERSE 29CD box for surgical instruments

Made from autoclavable material, this box contains all the rotating and non-rotating surgical instruments needed to carry out the surgical and prosthetic protocols for the UNIVERSE Line.

The figure of a drill with the various depth notch measurements is shown on the Kit.

A screen-printed QR code on the box provides a convenient link to the surgical protocol.

Supplied non-sterile



Precision drill

The precision drill serves to cut the cortical bone, and is therefore very sharp and pointed.

The design of the blades guarantees an effective cut at both the tip and the side.

It has a maximum diameter of 2.0 mm and a laser marking positioned at 10 mm indicating the maximum depth to which the drill can be inserted. The precision drill is used to obtain a suitable guide hole for the subsequent drills.

The drill is made from surgical steel with a DLC surface treatment and a clear laser-etched reference notch.

Supplied non-sterile



Ø2 cylindrical pilot drill

With its cylindrical shape and 2.00 mm diameter, the pilot drill is used to prepare the initial hole for the implant. The drill is easy to identify thanks to the diameter laser-marked on the shank of the drill itself.

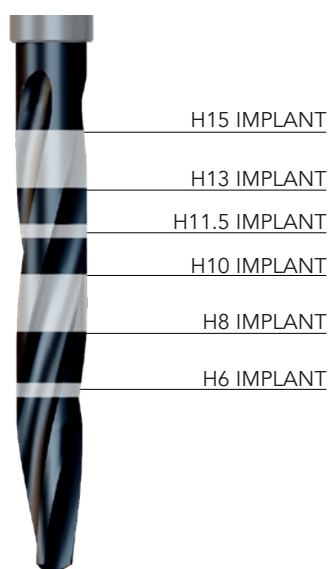
The drill features depth notches, and can be used in conjunction with fixed-depth stops.

It has laser-marked depth notches, and a helical shape with double-lead threads. It must be used with plenty of external irrigation.

The surgical drill is made from medical grade steel with a DLC (Diamond Like Carbon) coating, which gives the drill its characteristic black colour, and not only improves the visibility of the depth markings during use, but also enhances its mechanical performance and durability.

A coloured silicone O-ring is mounted on the drill, allowing the upper drill stops to stop in the correct position. The O-rings are red as they identify the CC RP platform, and can be re-ordered when worn.

Caution: when drilling in the vicinity of vital anatomical structures, the increased length of the drill, which varies from drill to drill, must be taken into account.



Supplied non-sterile



Red drill stops kit for Ø2.0 to Ø4.0 drills

Green stop drills kit for Ø4.4 drills

The drill stops are devices that can be inserted onto IML drills designed to accommodate them, and are inserted over the tip of the drill itself. They allow the working length of a drill to be limited to a predetermined depth.

The drill stops have two notches, which serve as a reference when inserting them (the drill stops are inserted onto the drill from the side opposite the notches), and improve the grip when removing them from the drill.

All of the drill stops are colour-coded based on the drill to be used, and each bushing has the height of the implant laser-printed on it.

It is recommended to always check that the stop has been inserted to the desired depth. Incomplete insertion could reduce the depth of the preparation. Any insertion difficulties can be resolved by thoroughly cleaning both components.

It is also recommended to check the retention exerted by the stop, as too weak a retention force can cause the instrument to fall off the drill during the surgery.

If the stops' retention capacity should decline, replacement O-rings can be ordered from IML SA. *Supplied non-sterile*



Drill extension

Manufactured in stainless steel. Allows the overall length of the drill to be increased.

Supplied non-sterile; must be autoclaved prior to use.

Supplied non-sterile



Guide pin

The parallelism pins can be used to check the placement axis of the implants and the parallelism between them.

The pins have a \varnothing 2.00 mm on both sides.

The standard IML parallelism pins have depth notches, which allow the height of the preparation to be controlled during the various steps.

As they are slightly smaller in diameter than the pin body, the notches are clearly visible on the intraoperative images.

The pin has two sides, one 7mm long and the other 15mm long, with notches from 6 to 13mm.

Supplied non-sterile



UNIVERSE cylindrical drills

UNIVERSE implant end drills are cylindrical in shape with a conical apex, and are used to prepare the final implant hole. The drill is easy to identify thanks to the diameter laser-marked on the shank of the drill itself.

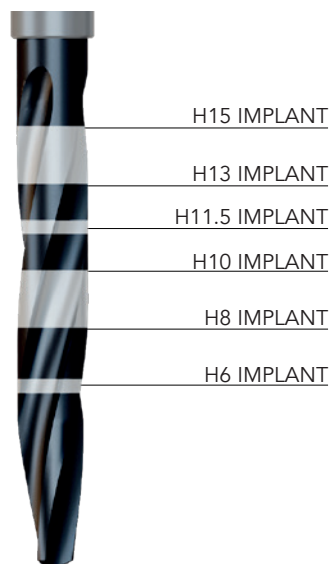
The drill features depth notches, and can be used in conjunction with fixed-depth stops.

It has laser-marked depth notches, and a helical shape with triple-lead threads. It must be used with plenty of external irrigation.

The surgical drill is made from medical grade steel with a DLC (Diamond Like Carbon) coating, which gives the drill its characteristic black colour, and not only improves the visibility of the depth markings during use, but also enhances its mechanical performance and durability.

A coloured silicone O-ring is mounted on the drill, allowing the upper drill stops to stop in the correct position. The red and green O-rings connect the drill to its bushing, and can be re-ordered when worn.

Caution: when drilling in the vicinity of vital anatomical structures, the increased length of the drill, which varies from method to method, must be taken into account.



Supplied non-sterile



Conical drill

The UNIVERSE end drills are conical in shape, and are designed according to the shape of the specific implant. Their purpose is to create the perfect osteotomy for the placement of the implant into the alveolus, thus limiting the surgical steps required. The drills are easy to identify thanks to the size laser-marked on the shank, indicating both the diameter relative to the implant and the length. The correct drilling depth corresponds to the actual length of the drill. Based on the shape of the drill, in particularly dense bone, particular resistance may be encountered in drilling to the maximum depth. In such cases it is recommended to drill the bone first using a drill of the same length but with a smaller diameter. The conical drills have a parallel shape with three cutting edges. They are made of medical surgical steel coated with fully biocompatible DLC (Diamond Like Carbon), which gives the drills their characteristic colouring and significantly improves mechanical performance and strength.

Caution: when drilling in the vicinity of vital anatomical structures, the increased length of the drill, which varies from drill to drill, must be taken into account.



Motor mount implant driver

The UNIVERSE implant does not require a carrier to be inserted into the implant site, as it is engaged directly in the connection by the dedicated implant drivers, which are specially designed to ensure a secure grip, not to deform the connection, and at the same time to allow for easy removal from the implant well. The use of these drivers makes the surgical insertion procedure extremely simple.

The implant drivers are made of surgical steel, are subjected to stringent strength tests before being released onto the market, and feature a sandblasted area at the grip zone to improve the engagement grip.

The friction zone with the implant is designed and positioned in a different zone than where the conometry of the prosthetic parts will act.

The instruments have a reference notch indicating the driver's correct insertion position.

With a simple push, the conometry is activated and the system can be safely withdrawn.

The implant drivers offer the possibility of orienting the hexagonal connection as desired, since they have a hexagonal index corresponding to the prosthetic index and the lines engraved on the component.

When using the Implant drivers, care should be taken to maintain the working axis as perpendicular as possible. It is also essential to avoid abrupt and uneven movements.

Failure to observe these usage precautions and exceeding the insertion torque could result in instrument failure.

Supplied non-sterile



Multitool implant driver

As described for the motor mount implant drivers, the UNIVERSE implant does not require a carrier to be inserted into the implant site, as it is engaged directly in the connection by the dedicated implant drivers. The use of these drivers makes the surgical insertion procedure extremely simple.

The multitool implant drivers are made of surgical steel, are subjected to stringent strength tests before being released onto the market, and feature a sandblasted area at the grip zone to improve the engagement grip.

The friction zone with the implant is designed and positioned in a different zone than where the conometry of the prosthetic parts will act.

The instruments have a reference notch indicating the driver's correct insertion position.

With a simple push, the conometry is activated and the system can be safely withdrawn.

The implant drivers offer the possibility of orienting the hexagonal connection as desired, since they have a hexagonal index corresponding to the prosthetic index and the lines engraved on the component.

The multitool implant drivers have a colour-coded O-ring to indicate the relative platform of use.

When using the Implant drivers, care should be taken to maintain the working axis as perpendicular as possible.

It is essential to use a slow and even movement with the ratchet when tightening, avoiding abrupt movements as much as possible. Failure to observe these usage precautions and exceeding the insertion torque could result in instrument failure.

In order to ensure greater stability during tightening, it is recommended to maintain light and constant pressure on the end inserted in the torque ratchet with one finger.

Supplied non-sterile



Dynamometric ratchet Fixed ratchet

Supplied non-sterile



Digital adapter for multitool drivers

Made from grade 5 medical titanium, this adapter allows instruments with multitool (ratchet) connections to be used manually.

Supplied non-sterile



Multitool driver for screws

All the screw drivers are made of electropolished and hardened surgical steel, and the design of the part connecting the driver to the screws is designed to engage a screw with a 1.26mm internal hexagonal connection.

The slightly conical coupling between the driver and screw allows for adequate retention of the latter within the oral cavity.

It is important to check regularly that this functionality has not been lost due to wear and tear, otherwise the unit should be replaced.

The upper knurled area also allows the driver to be used digitally.

The drivers are available with shanks of different lengths in order to facilitate ergonomics based on the patient's anatomy.

Important warning:

Excessive torque can strip the shafts of the clamping screws and round off the corners of the screwdrivers, causing potentially serious intraoperative or prosthetic complications.

The recommended torques for tightening the various components must be scrupulously respected, without ever exceeding 35 Ncm.

Lever-type movements should be avoided, as they increase the risk of fracture.

Make sure that the hexagonal profile of the driver tip has been properly inserted into the hexagon of the screws to be tightened before tightening.

Incorrect insertion can lead cause the hexagon of the screwdriver or the screw to be stripped.

The drivers have a slightly conical profile, which ensures that the hexagon of the driver fits inside the hexagon on the screw heads, so that the screw can be brought safely into the mouth without getting lost inside the oral cavity.

Supplied non-sterile



Motor driver for screws

All the screw drivers are made of electropolished and hardened surgical steel, and the design of the part connecting the driver to the screws is designed to engage a screw with a 1.26mm internal hexagonal connection.

The slightly conical coupling between the driver and screw allows for adequate retention of the latter within the oral cavity.

It is important to check regularly that this functionality has not been lost due to wear and tear, otherwise the unit should be replaced.

The micromotor mount drivers are made from surgical steel, and are compliant with the contra-angle handpiece compatibility standard (ISO 1797-1).

The drivers are intended exclusively for use with micromotors, and are available with shanks of different lengths in order to facilitate ergonomics based on the patient's anatomy.

Important warning:

Excessive torque can strip the shafts of the clamping screws and round off the corners of the screwdrivers, causing potentially serious intraoperative or prosthetic complications. The recommended torques for tightening the various components must be scrupulously respected, without ever exceeding 35 Ncm.

Lever-type movements should be avoided, as they increase the risk of fracture.

Make sure that the hexagonal profile of the driver tip has been properly inserted into the hexagon of the screws to be tightened before tightening.

Incorrect insertion can lead cause the hexagon of the screwdriver or the screw to be stripped.

The drivers have a slightly conical profile, which ensures that the hexagon of the driver fits inside the hexagon on the screw heads, so that the screw can be brought safely into the mouth without getting lost inside the oral cavity.

Supplied non-sterile



Smartpegs for implants

SmartPegs are measuring devices. They are made of a delicate material, so the threads have a limited life span. The Osstell instrument vibrates the SmartPeg with magnetic pulses, and measures its resonance frequency. In order to function properly, the SmartPeg must be firmly connected to the implant or abutment.

Always make sure that the correct type of SmartPeg is used. If any resistance is encountered when mounting the SmartPeg, do not use excessive force to screw it in, as this could damage it. If the SmartPeg's threading is damaged, the SmartPeg may not function correctly, resulting in incorrect ISQ results.

SmartPegs are made from soft metal, and have a zinc-coated magnet at the top. SmartPegs are therefore subject to rapid wear and tear once opened. For this reason, as well as for hygiene purposes, the SmartPegs must be disposed of after use. The SmartPeg's sterile packaging remains sterile for at least 5 years. The expiry date is printed on the SmartPeg's blister packaging. During this period, some parts of the SmartPeg may change colour. For example, small visible stains may form on the body of the SmartPeg due to oxidation, which in no way compromise the functionality or sterility of the SmartPeg itself.

Used SmartPegs must be recycled as metal.

- The SmartPeg is made of soft aluminium. It must be softer than the implant in order to avoid damaging any parts of it, such as its connection.
- Autoclave treatment may accelerate both the wear and corrosion of aluminium due to the rather extreme conditions present during the autoclaving process.
- SmartPeg wear manifests itself in the form of the "detachment" of small fragments of aluminium, which remain within the implant and its connection.
- As the integrity of the product is not guaranteed after repeated use and/or autoclaving, this method is only approved for use with new SmartPegs.
- There are naturally other (cold) sterilisation methods as well, but these are not 100% functional in terms of sterilisation, and still have potential problems associated in terms of mechanical wear.



Multitool extractor for abutments

The engagement of the prosthetic components in the implant with IML Conical Connections results in a firm and stable coupling, which ensures the proper sealing of the implant and stability for the prosthesis.

The final coupling can be removed with a dedicated manual extractor. The red O-ring identifies instruments suitable for the CC RP connection (M1.8 thread)

The upper knurled area also allows the driver to be used digitally.

Supplied non-sterile



Multitool driver for straight MUAs

This mounting driver for MUAs can be used directly on the micromotor, and is used to permanently apply straight MUA abutments.

The upper knurled area also allows the driver to be used digitally.

Important warning:

Excessive torques can strip the hexagonal wrench for the abutments.

The recommended torques for tightening the various components must be scrupulously respected, without ever exceeding 35 Ncm.

Supplied non-sterile



Motor mount driver for straight MUAs

This mounting driver for MUAs can be used directly on the micromotor, and is used to permanently apply straight MUA abutments.

The micromotor mount drivers are made from surgical steel, and are compliant with the contra-angle handpiece compatibility standard (ISO 1797-1).

Important warning

Excessive torques can strip the hexagonal wrench for the abutments.

The recommended torques for tightening the various components must be scrupulously respected, without ever exceeding 35 Ncm.

Supplied non-sterile



UNIVERSE threadformer

The threadformer, made of medical steel, can be used manually with either the digital adapter or the ratchet.

They are mainly used in the presence of compact bone to prevent implant placement from being carried out in a forced manner and causing compressive stress in the bone, thus compromising healing

UNIVERSE implants are easy-to-insert self-tapping implants with an excellent cutting capacity; however, the use of the threadformer is recommended in all cases where the type of bone requires it, in order to facilitate the fixture's insertion. They are DLC-coated and have laser-printed reference notches.

The red O-ring in the ratchet connection identifies instruments suitable for the DC RP connection.

Supplied non-sterile



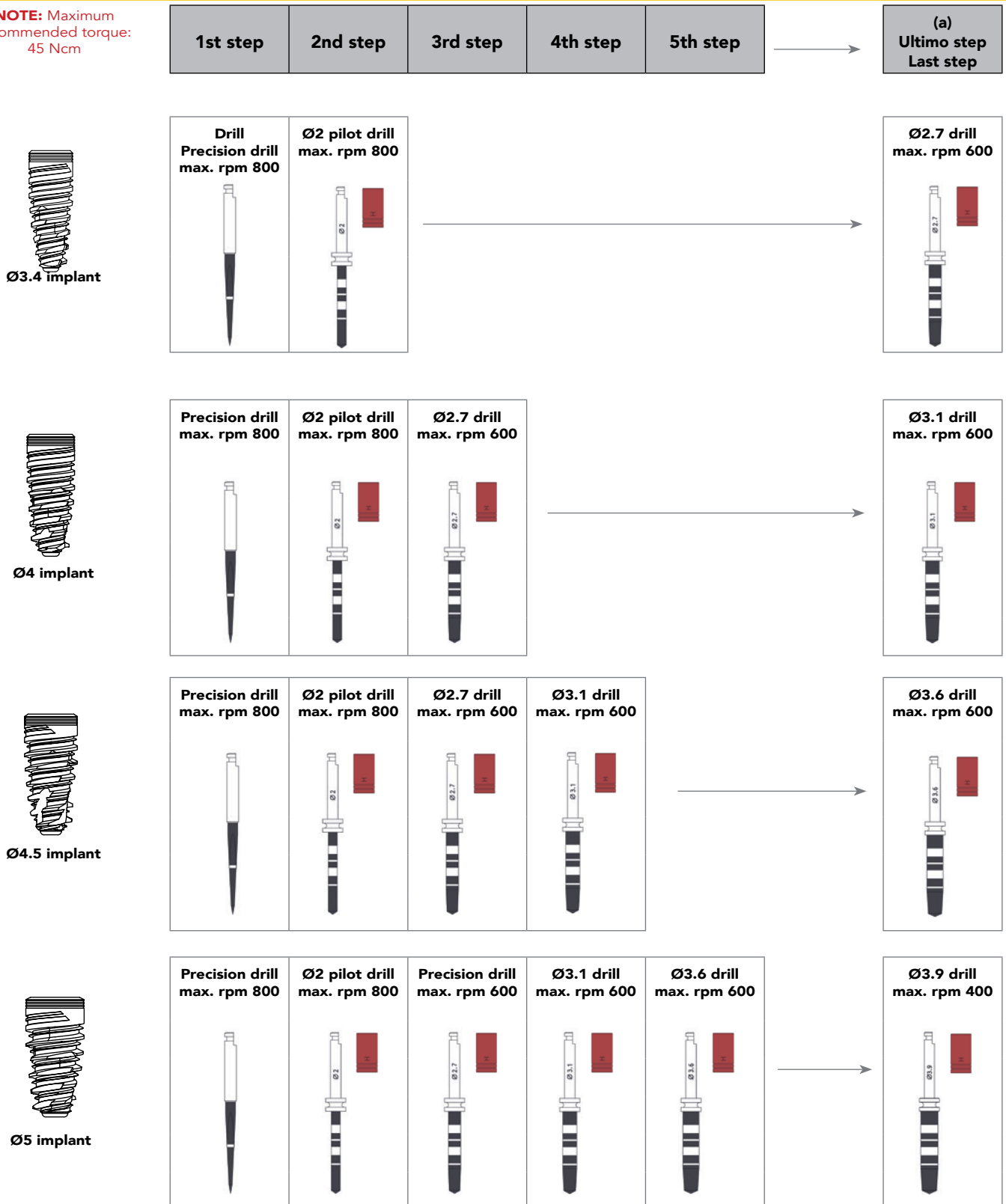
GENERAL OUTLINE OF THE CD (CYLINDRICAL DRILL) SURGICAL PROTOCOL

The UNIVERSE CD surgical protocol was developed in order to provide the surgeon with guidance on the selection of the most suitable instruments for implant site preparation based on different bone qualities. However, it is up to the surgeon to determine the most suitable surgical protocol based on his or her experience, by carefully evaluating the individual patient's clinical situation.

For the preparation of the implant site, cylindrical drills with a tapered conical apex were developed, with depth reference marks based on the length of the implant, and the possibility of using stop drill stops.

D4-D3


















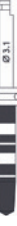










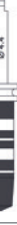

NOTE: Maximum recommended torque: 45 Ncm



In cases of dense D1 bone, adequate cortical preparation is particularly important to prevent the implant from impacting it. In this regard, IML's technical department has developed special threadformers, whose use allows implants to be easily inserted into particularly hard bone.

D2-D1

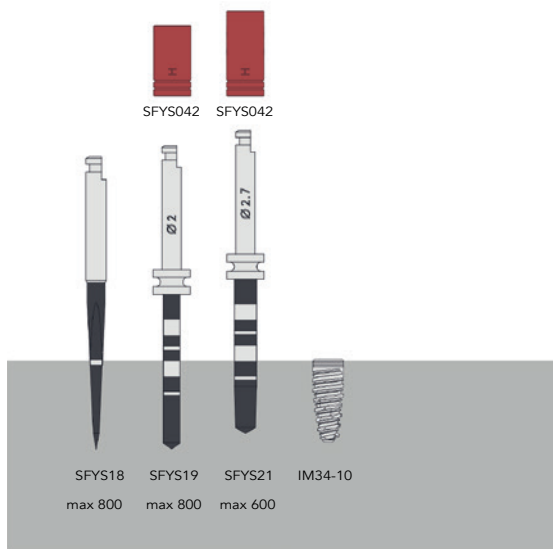
NOTE:

	1st step	2nd step	3rd step	4th step	5th step	6th step	(a) Ultimo step Last step	(b) Step corticale Cortical step	
 Ø3.4 implant	Precision drill max. rpm 800 	Ø2 pilot drill max. rpm 800 	Ø2.7 drill max. rpm 600 			Ø3.1 drill max. rpm 600 	Ø3.6 drill max. rpm 600 		
 Ø4 implant	Precision drill max. rpm 800 	Ø2 pilot drill max. rpm 800 	Ø2.7 drill max. rpm 600 	Ø3.1 drill max. rpm 600 			Ø3.6 drill max. rpm 600 	Ø3.9 drill max. rpm 400 	
 Ø4.5 implant	Precision drill max. rpm 800 	Ø2 pilot drill max. rpm 800 	Ø2.7 drill max. rpm 600 	Ø3.1 drill max. rpm 600 	Ø3.6 drill max. rpm 600 			Ø3.9 drill max. rpm 400 	Ø4.4 drill max. rpm 400  (c)
 Ø5 implant	Precision drill max. rpm 800 	Ø2 pilot drill max. rpm 800 	Ø2.7 drill max. rpm 600 	Ø3.1 drill max. rpm 600 	Ø3.6 drill max. rpm 600 	Ø3.9 drill max. rpm 400 	Ø4.4 drill max. rpm 400 	Ø4.9 drill max. rpm 400 	

NOTE: PAY ATTENTION TO THE DEPTH INTERVALS OF THE DRILLS

Application example for
UNIVERSE Ø3.4 - h10

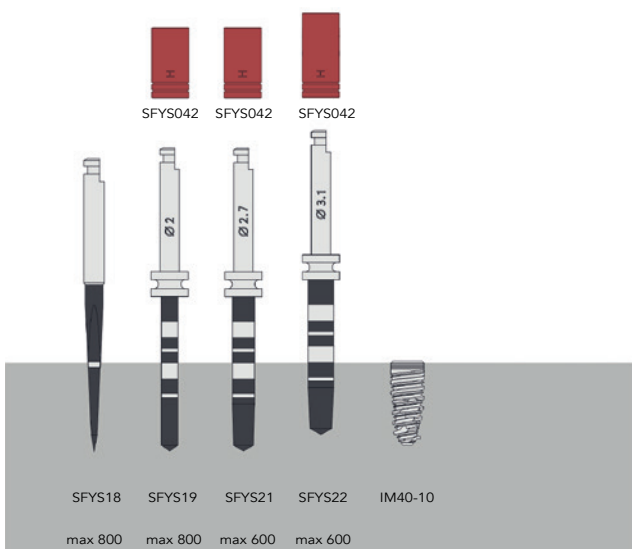
D4-D3



- SFYS18 Fresa lanceolata
Precision drill
- SFYS042 Bussola stop
Drill stop
- SFYS19 Fresa pilota cilindrica Ø2
Cylindrical pilot drill Ø2
- SFYS21 Fresa cilindrica Ø2.7
Cylindrical drill Ø2.7
- IM34-10 Impianto Ø3.4 - h10
Implant Ø3.4 - h10

Application example for
UNIVERSE Ø4 - h10

D4-D3

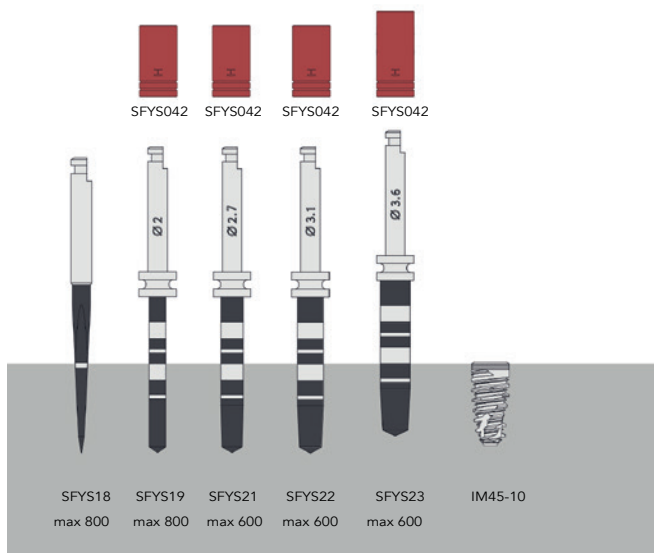


- SFYS18 Fresa lanceolata
Precision drill
- SFYS042 Bussola stop
Drill stop
- SFYS19 Fresa pilota cilindrica Ø2
Cylindrical pilot drill Ø2
- SFYS21 Fresa cilindrica Ø2.7
Cylindrical drill Ø2.7
- SFYS22 Fresa cilindrica Ø3.1
Cylindrical drill Ø3.1
- IM40-10 Impianto Ø4 - h10
Implant Ø4 - h10

NOTE: PAY ATTENTION TO THE DEPTH INTERVALS OF THE DRILLS

Application example for
UNIVERSE Ø4.5 - h10

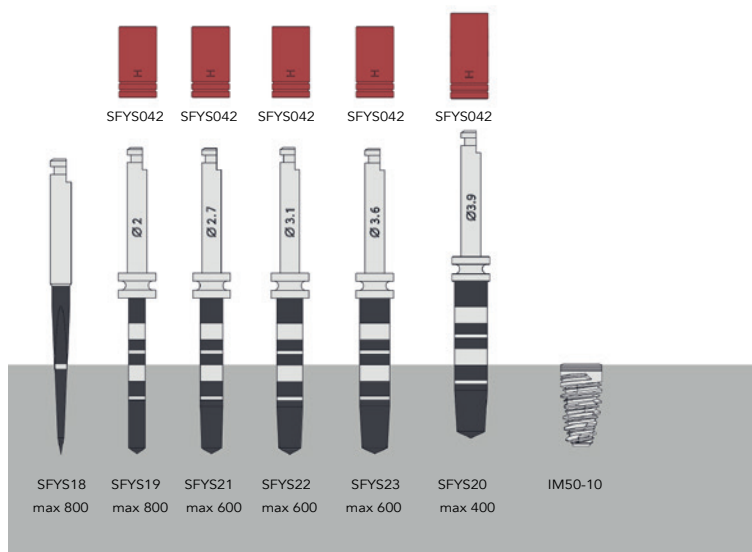
D4-D3



- SFYS18 Fresa lanceolata
Precision drill
- SFYS042 Bussola stop
Drill stop
- SFYS19 Fresa pilota cilindrica Ø2
Cylindrical pilot drill Ø2
- SFYS21 Fresa cilindrica Ø2.7
Cylindrical drill Ø2.7
- SFYS22 Fresa cilindrica Ø3.1
Cylindrical drill Ø3.1
- SFYS23 Fresa cilindrica Ø3.6
Cylindrical drill Ø3.6
- IM45-10 Impianto Ø4.5 - h10
Implant Ø4.5 - h10

Application example for
UNIVERSE Ø5 - h10

D4-D3

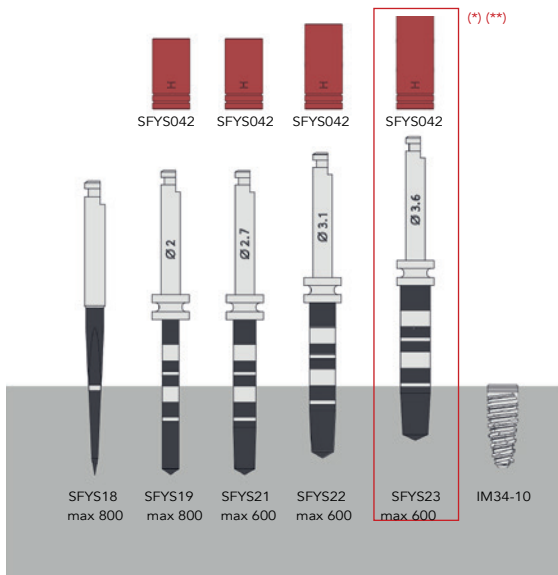


- SFYS18 Fresa lanceolata
Precision drill
- SFYS042 Bussola stop
Drill stop
- SFYS043 Bussola stop
Drill stop
- SFYS19 Fresa pilota cilindrica Ø2
Cylindrical pilot drill Ø2
- SFYS21 Fresa cilindrica Ø2.7
Cylindrical drill Ø2.7
- SFYS22 Fresa cilindrica Ø3.1
Cylindrical drill Ø3.1
- SFYS23 Fresa cilindrica Ø3.6
Cylindrical drill Ø3.6
- SFYS20 Fresa cilindrica Ø3.9
Cylindrical drill Ø3.9
- IM50-10 Impianto Ø5 - h10
Implant Ø5 - h10

NOTE: PAY ATTENTION TO THE DEPTH INTERVALS OF THE DRILLS

Application example for
UNIVERSE Ø3.4 - h10

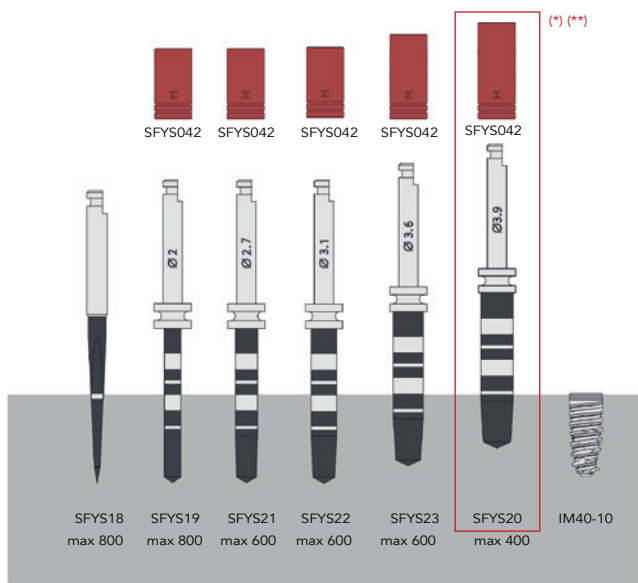
D2-D1



- SFYS18 Fresa lanceolata
Precision drill
- SFYS042 Bussola stop
Drill stop
- SFYS19 Fresa pilota cilindrica Ø2
Cylindrical pilot drill Ø2
- SFYS21 Fresa cilindrica Ø2.7
Cylindrical drill Ø2.7
- SFYS22 Fresa cilindrica Ø3.1
Cylindrical drill Ø3.1
- SFYS23 Fresa cilindrica Ø3.6
Cylindrical drill Ø3.6
- IM34-10 Impianto Ø3.4 - h10
Implant Ø3.4 - h10

Application example for
UNIVERSE Ø4 - h10

D2-D1



- SFYS18 Fresa lanceolata
Precision drill
- SFYS042 Bussola stop
Drill stop
- SFYS19 Fresa pilota cilindrica Ø2
Cylindrical pilot drill Ø2
- SFYS21 Fresa cilindrica Ø2.7
Cylindrical drill Ø2.7
- SFYS22 Fresa cilindrica Ø3.1
Cylindrical drill Ø3.1
- SFYS23 Fresa cilindrica Ø3.6
Cylindrical drill Ø3.6
- SFYS20 Fresa cilindrica Ø3.9
Cylindrical drill Ø3.9
- IM40-10 Impianto Ø4 - h10
Implant Ø4 - h10

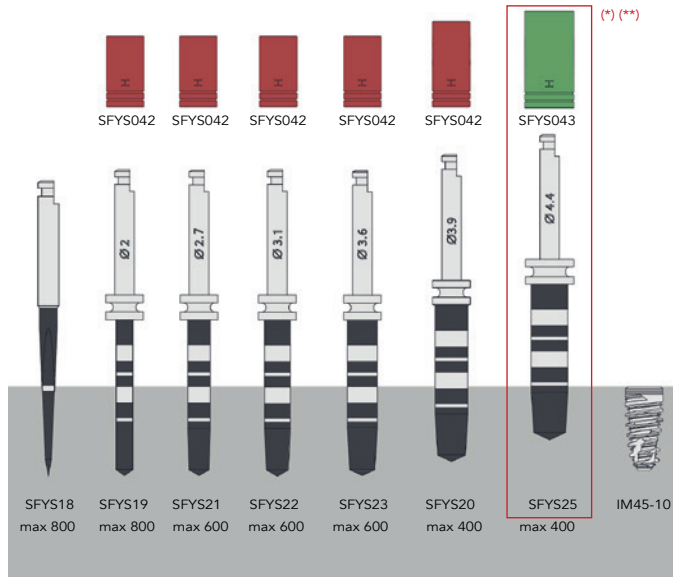
(*): this box represents the cortical step: use notch 6 as a reference, regardless of the height of the implant.

(**) the threadformer should be used if the standard protocol for dense bone is not sufficient to insert the implant completely without exceeding the maximum recommended insertion torque

NOTE: PAY ATTENTION TO THE DEPTH INTERVALS OF THE DRILLS

Application example for
UNIVERSE Ø4.5 - h10

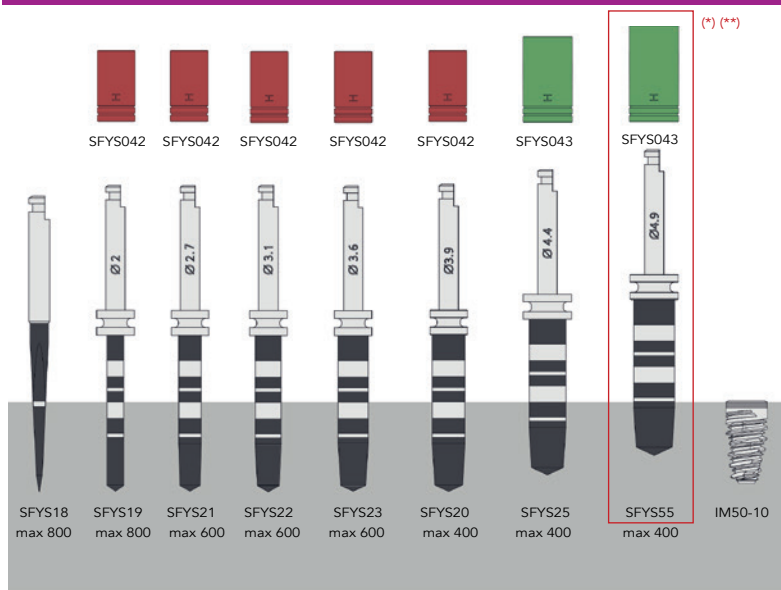
D2-D1



SFYS18	Fresa lanceolata Precision drill
SFYS042	Bussola stop Drill stop
SFYS043	Bussola stop Drill stop
SFYS19	Fresa pilota cilindrica Ø2 Cylindrical pilot drill Ø2
SFYS21	Fresa cilindrica Ø2.7 Cylindrical drill Ø2.7
SFYS22	Fresa cilindrica Ø3.1 Cylindrical drill Ø3.1
SFYS23	Fresa cilindrica Ø3.6 Cylindrical drill Ø3.6
SFYS20	Fresa cilindrica Ø3.9 Cylindrical drill Ø3.9
SFYS25	Fresa cilindrica Ø4.4 Cylindrical drill Ø4.4
IM45-10	Impianto Ø4.5 - h10 Implant Ø4.5 - h10

Application example for
UNIVERSE Ø5 - h10

D2-D1



SFYS18	Fresa lanceolata Precision drill
SFYS042	Bussola stop Drill stop
SFYS043	Bussola stop Drill stop
SFYS19	Fresa pilota cilindrica Ø2 Cylindrical pilot drill Ø2
SFYS21	Fresa cilindrica Ø2.7 Cylindrical drill Ø2.7
SFYS22	Fresa cilindrica Ø3.1 Cylindrical drill Ø3.1
SFYS23	Fresa cilindrica Ø3.6 Cylindrical drill Ø3.6
SFYS20	Fresa cilindrica Ø3.9 Cylindrical drill Ø3.9
SFYS25	Fresa cilindrica Ø4.4 Cylindrical drill Ø4.4
SFYS55	Fresa cilindrica Ø4.9 Cylindrical drill Ø4.9
IM50-10	Impianto Ø5 - h10 Implant Ø5 - h10

(*): this box represents the cortical step: use notch 6 as a reference, regardless of the height of the implant.

(**): the threadformer should be used if the standard protocol for dense bone is not sufficient to insert the implant completely without exceeding the maximum recommended insertion torque.

TD (TAPERED DRILL) SURGICAL PROTOCOL

















The UNIVERSE TD surgical protocol was developed with the aim of providing the surgeon with the most appropriate instruments possible with respect to the bone, which are also practical and easy to use.

The preparation of the implant site for the UNIVERSE implant is therefore completed in 3 simple steps, after which the implant can be easily inserted.

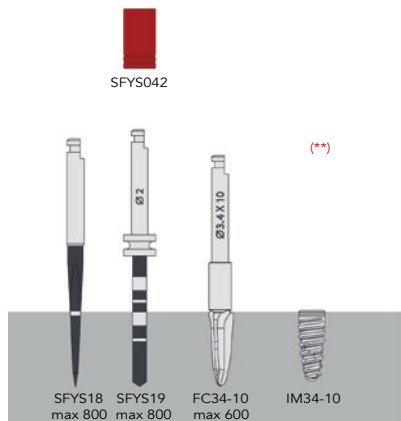
The implant site is prepared using tapered drills, which optimise the bone available for the placement of the implant with zero waste. These drills are sized according to each individual implant diameter and height, in order to facilitate the drilling protocol, reducing it to three simple steps. The tip's special shape guides its progressive advancement, respecting the bone, and preparing a customised implant site. However, it is up to the surgeon to determine the most suitable surgical protocol based on his or her experience, by carefully evaluating the individual patient's clinical situation.

In cases of dense D1 bone, adequate cortical preparation is particularly important to prevent the implant from impacting it. In this regard, IML's technical department has developed special threadformers, whose use allows implants to be easily inserted into particularly hard bone.

- no stop for the end drill

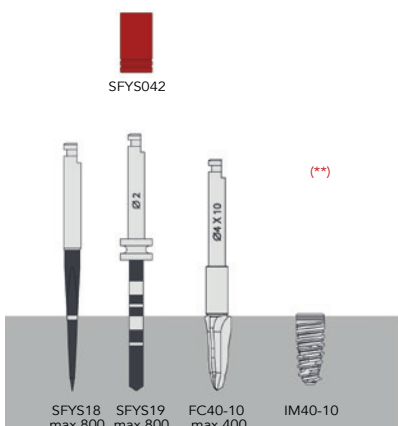
	1st step	2nd step	3rd step
 <p>Ø3.4 implant</p>	<p>Precision drill max. rpm 800</p> 	<p>Pilot drill Ø2 max. rpm 800</p> 	<p>Ø3.4 drill max. rpm 600</p> 
 <p>Ø4 implant</p>	<p>Precision drill max. rpm 800</p> 	<p>Pilot drill Ø2 max. rpm 800</p> 	<p>Ø4.0 drill max. rpm 400</p> 
 <p>Ø4.5 implant</p>	<p>Precision drill max. rpm 800</p> 	<p>Pilot drill Ø2 max. rpm 800</p> 	<p>Ø4.5 drill max. rpm 400</p> 
 <p>Ø5 implant</p>	<p>Precision drill max. rpm 800</p> 	<p>Pilot drill Ø2 max. rpm 800</p> 	<p>Ø5.0 drill max. rpm 400</p> 

Application example for UNIVERSE Ø3.4 - h10



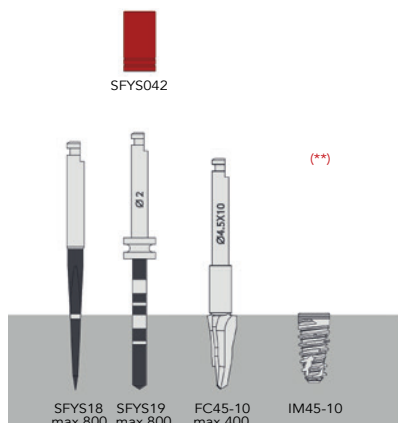
SFYS18	Fresa lanceolata Precision drill
SFYS042	Bussola stop Drill stop
SFYS19	Fresa pilota cilindrica Ø2 Cylindrical pilot drill Ø2
FC34-10	Fresa conica Ø3.4 - h10 Conical drill Ø3.4 - h10
IM34-10	Impianto Ø3.4 - h10 Implant Ø3.4 - h10

UNIVERSE Ø4.0 - h10



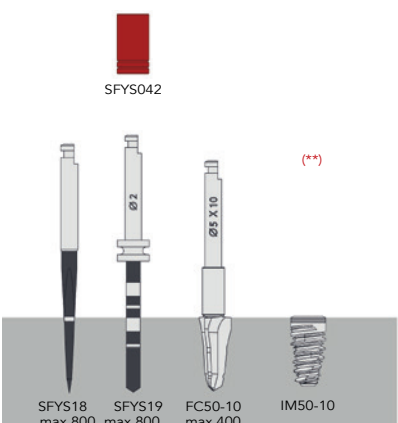
SFYS18	Fresa lanceolata Precision drill
SFYS042	Bussola stop Drill stop
SFYS19	Fresa pilota cilindrica Ø2 Cylindrical pilot drill Ø2
FC40-10	Fresa conica Ø4.0 - h10 Conical drill Ø4.0 - h10
IM40-10	Impianto Ø4.0 - h10 Implant Ø4.0 - h10

UNIVERSE Ø4.5 - h10



SFYS18	Fresa lanceolata Precision drill
SFYS042	Bussola stop Drill stop
SFYS19	Fresa pilota cilindrica Ø2 Cylindrical pilot drill Ø2
FC45-10	Fresa conica Ø4.5 - h10 Conical drill Ø4.5 - h10
IM45-10	Impianto Ø4.5 - h10 Implant Ø4.5 - h10

UNIVERSE Ø5.0 - h10



SFYS18	Fresa lanceolata Precision drill
SFYS042	Bussola stop Drill stop
SFYS19	Fresa pilota cilindrica Ø2 Cylindrical pilot drill Ø2
FC50-10	Fresa conica Ø5.0 - h10 Conical drill Ø5.0 - h10
IM50-10	Impianto Ø5.0 - h10 Implant Ø5.0 - h10

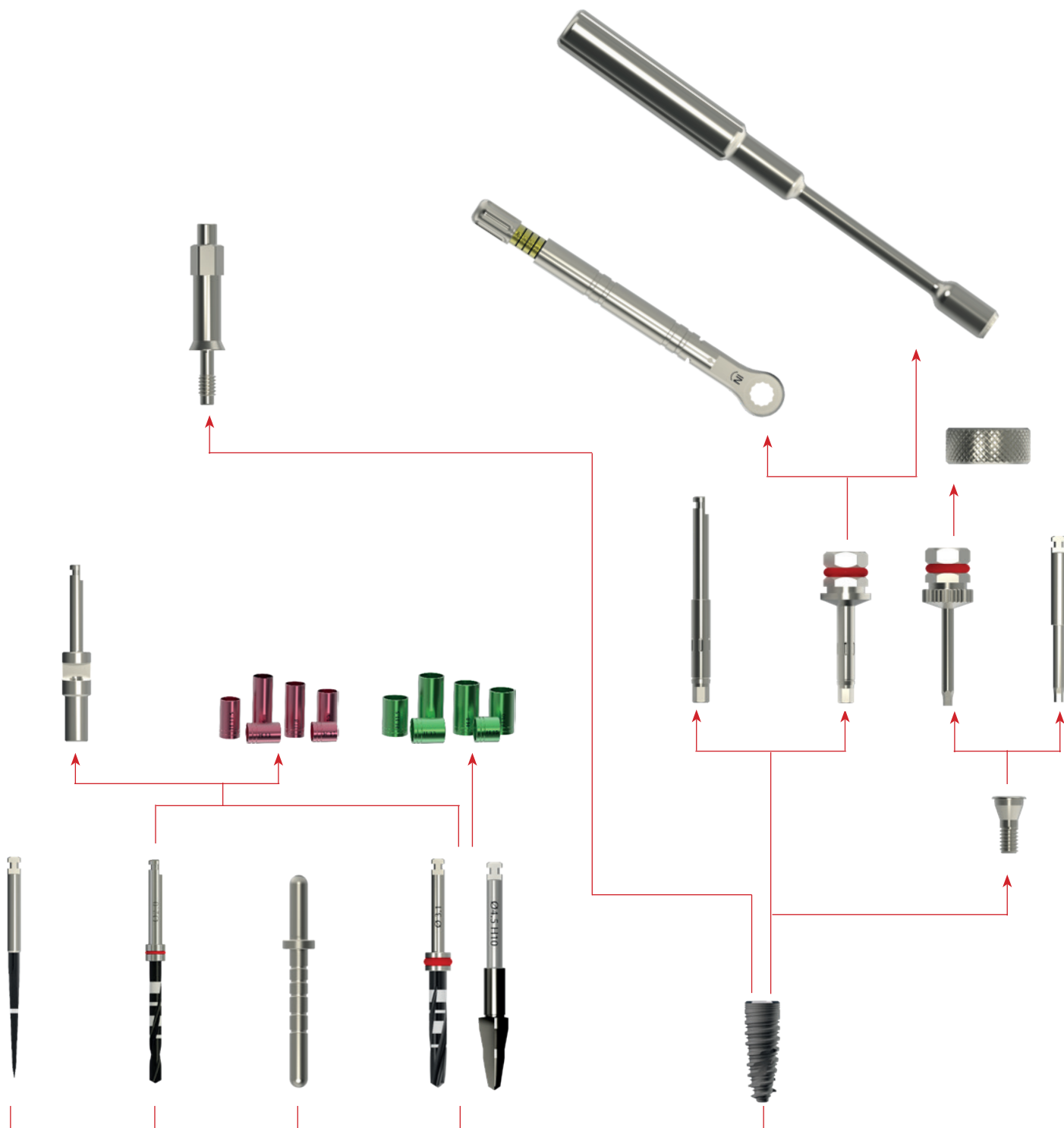
(**) the threadformer should be used if the standard protocol for dense bone is not sufficient to insert the implant completely without exceeding the maximum recommended insertion torque.

PREPARATION OF THE UNIVERSE IMPLANT BED

Preparation of the implant bed for a $\text{\O}4.0\text{mm}$ h10mm UNIVERSE implant in very hard bone (D1). After opening the flap, the preparation of the implant site begins with a precision drill, which serves to cut the cortical bone and create the opening for the subsequent use of the pilot drill, ensuring a quick and precise cut (step 1).

The pilot drill and cylindrical or conical drills (steps 2 and 4) are then used, depending on the surgical protocol to be used and the diameter of the implant to be placed. The implant site is prepared with drills of increasing diameter (step 5).

In mandibles with particularly hard bone (D1), it is recommended to use the threadformer (step 6).



PREPARATION OF THE UNIVERSE IMPLANT BED



Fig.1

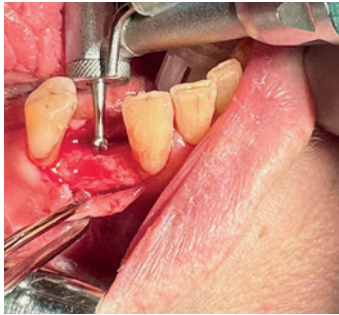


Fig.2

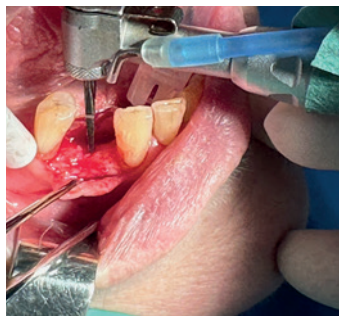


Fig.3



Fig.4

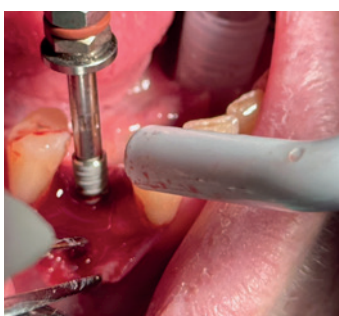


Fig.5

STEP 1: This consists of determining the precise implant insertion point. In the case of a very thin alveolar ridge, it is recommended to flatten it carefully using, for example, a round or flame bur mounted on a turbine (used transversely), in order to obtain a flat bone surface. Immediately afterwards, the precise implant preparation point can be marked with a small $\text{Ø}1.4$ mm round bur. This last step cannot be carried out in the case of post-extraction implant placement. (Fig. 1 and 2)

STEP 2: Use the precision drill to cut the cortical bone and create the opening for the subsequent use of the pilot drill. This can also be used in the absence of a flat or even surface. (Fig. 3)

STEP 3: during this step, the depth of the implant preparation and its axis are determined. The $\text{Ø} 2$ mm pilot drill is used, drilling to a depth of about 6 mm. The direction of preparation is checked with an alignment pin. The pilot drill is then used to drill to the final preparation depth. It may be useful to check the preparation axis and depth several times with the parallelism pin. It is recommended to perform an endoral X-ray with the pin inserted into the implant site to compare the preparation with the neighbouring anatomical structures. (Fig. 4)

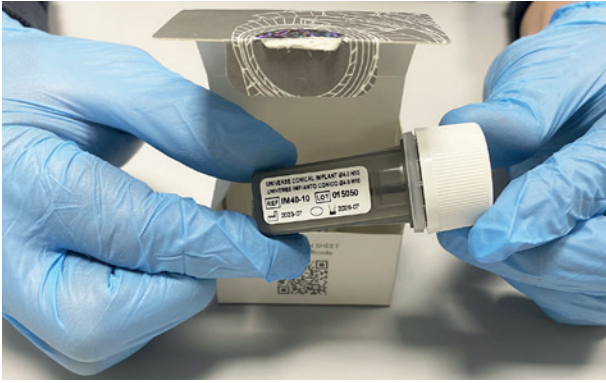
STEP 4: enlarge the implant site to the previously determined depth with the tapered $\text{Ø} 2.7$ mm drill. Pay close attention to the vascular and nerve structures near the implant site during this stage (the stops in the IML kit are useful). (Fig. 4)

STEP 5: The implant site is further enlarged with a $\text{Ø} 3.1$ mm drill. At this stage, the position of the implant site can be slightly corrected. Further endoral X-rays can be performed to verify the preparation's correct positioning. (Fig. 4)

STEP 6: the implant site is further enlarged with drills of increasing diameter until the hole diameter dictated by the protocol for the relative implant is reached. Care must be taken to avoid preparing too much vestibularly (for proper aesthetics), and to ensure that no less than one millimetre of bone is left on both the vestibular and palatal surfaces. (Fig. 4)

STEP 7: not always necessary. This step consists of shaping the most superficial part of the implant site with a threadformer. It is performed when the patient's autologous bone is particularly hard and compact. For example in the mandible with D1 bone. With subsequent placement of the dental implant in situ. (Fig.5)

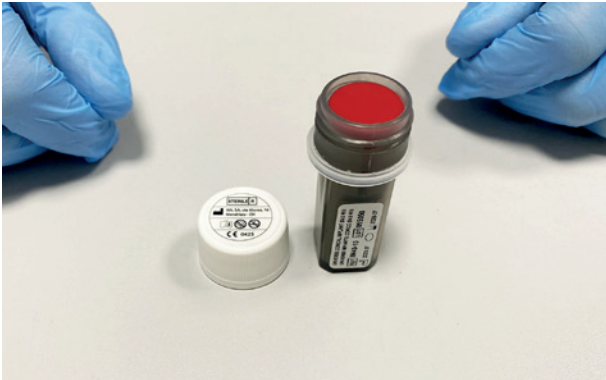
UNIVERSE IMPLANT EXTRACTION AND PLACEMENT PROCEDURE



- Check the packaging for the implant's description, length, diameter, and sterilisation expiry date.

If the packaging or tamper-evident seal is damaged, its contents may no longer be sterile, and the product should therefore not be utilised.

Open the package and take out the transparent grey polypropylene (PP) container, closed with a white polypropylene (PP) cap with a security seal, and the adhesive labels bearing the implant identification code and lot number, one of which can be placed on the doctor's medical chart and the other on the patient's implant passport.



- Opening the container:

the practitioner unscrews the white polypropylene (PP) cap with safety seal, thus exposing the grey ABS container containing the implant and the red ABS container containing the screw cap. The dental implants are positioned between two titanium spacers.



- Set the torque value on the torque ratchet or micromotor (max. speed 25 rpm) to 45 Ncm for UNIVERSE implants and 35 Ncm for UNIVERSE 2.9 implants.



- Mount the multitool implant driver on the ratchet or the motor mount implant driver on the handpiece.



- After having checked the product's description on the label, the practitioner can extract the container containing the implant.



- The practitioner extracts the red plug containing the screw cap, placing it on a sterile towel so that it will only be handled by the practitioner while wearing sterile gloves from that point onward.



- Insert the multitool implant driver or motor mount implant driver into the implant's connection, taking care to engage the hexagon correctly: the sandblasted portion should be inserted all the way to the reference notch.



- Pull the implant out of the implant retainer by pressing on the ends of the grey element ("spring action").

IMMEDIATE PLACEMENT IN POST-EXTRACTION SITES

STEP 1 : Preparation of the implant bed:

Immediately after extracting the tooth to be replaced with the implant, check haemostasis and proceed with site preparation. Start with a small-diameter round bur to create an anchor point in the apical part of the alveolus. Then use the precision drill in the palatal direction, and straighten the drill based on the axis of the planned implant site. Drill about 2-3 mm of the length of the implant, watching for any nerves that may be present.

STEP 2 : Implant axis and depth:

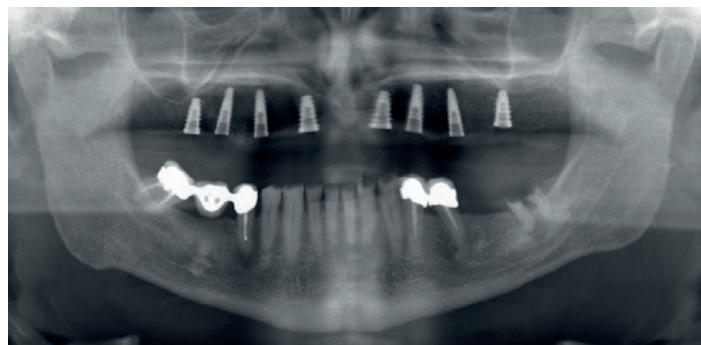
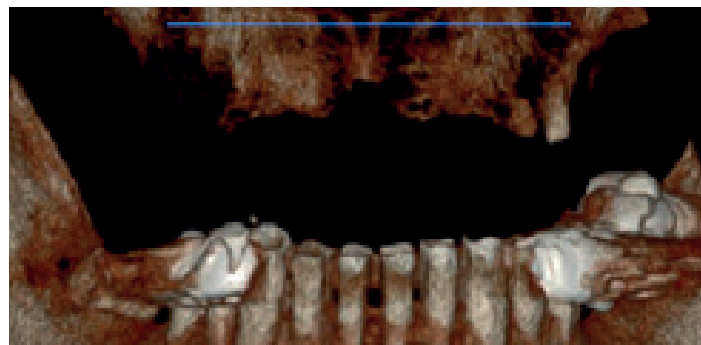
After having marked the preparation point with the precision drill, use the \varnothing 2.0 mm pilot drill to pre-drill the implant bed on the palatal side of the alveolus. Begin the preparation palatally, and after 1-2 mm correct the axis based on the prosthesis to be utilised. Use an alignment pin to ensure correct preparation. It is also useful to perform an endoral X-ray at this stage to check the correct orientation of the implant axis and the depth of the preparation. Next, the implant site is enlarged using low-speed micromotor mounted drills of increasing diameter and abundant irrigation with saline solution.

STEP 3: Implant insertion:

After preparing the implant site, remove the implant from the sterile ampoule containing the implant and insert it, first tilting at the palatal level. Once a fair degree of primary stability has been acquired, drive the implant down to the final position of the implant site.

The entire surface of the implant must be covered with autologous bone. If any titanium threads remain exposed, the gap must be filled with bone and membrane substitutes. This procedure requires a certain amount of experience and manual dexterity on the part of the surgeon.

At the end of the post-extraction implant insertion, and following the application of the screw cap, it is useful to have an endoral, bite-wing type x-ray performed.



SOFT TISSUE TREATMENT

After having verified that the implant's placement is correct via X-ray, the implant must be completed with one of the following:

1. a screw cap and subgingival healing,
2. a healing screw and transgingival healing,
3. prosthetic components to immediately render the implant functional, with immediate loading, which is only guaranteed if the connection screw is able to be tightened with the recommended torque.

SUBGINGIVAL HEALING WITH SCREW CAP

This consists of placing the screw cap, supplied along with all the implants, on the implant's red screw retainer. The mucoperiosteal flap covers the surgical surface, and this procedure is indicated in grafting situations with GBR, or when the implant itself does not have a high degree of primary stability. With this treatment, it is necessary to have the patient return after a few months to load the implant itself.

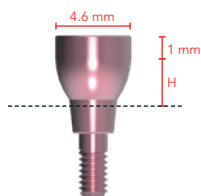
TRANSGINGIVAL HEALING WITH HEALING SCREW

It is possible to conclude the procedure by placing a healing screw on the implant, thus allowing for the modelling of soft tissue during healing. This is a procedure that can be applied when the implant has good primary stability, and when no bone substitute has been used for regeneration purposes.

TRANGINGIVAL HEALING AND IMMEDIATE LOADING

If the procedure concludes with good primary stability, with sufficient autologous bone in the aesthetic area, the abutment can be introduced, and the provisional restoration mounted.

The IML implant line offers a wide range of components for immediate loading. For further details on how to carry out immediate loading, please refer to the specific texts on oral surgery and prosthetics.

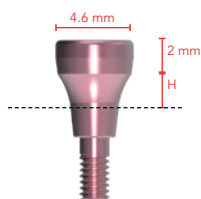


Healing screws

convex profile

Using a 1.26 mm hexagon screwdriver, tighten to a torque of 10 Ncm.

		H				
		1	2	3	4	5
Platform	RP	MGIU-1	MGIU-2	MGIU-3	MGIU-4	MGIU-5

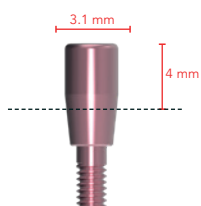


Shift healing screws

concave profile

Using a 1.26 mm hexagon screwdriver, tighten to a torque of 10 Ncm.

		H				
		1	2	3	4	5
Platform	RP	MGIU-21	MGIU-22	MGIU-23	MGIU-24	MGIU-25



Slim healing Screw

only for use with dedicated slim abutments

Using a 1.26 mm hexagon screwdriver, tighten to a torque of 10 Ncm.

Platform	RP	MGIU-0
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Healing screws for peek bridges

screw without engagement, it is therefore rotatable and millable
Using a 1.26 mm hexagon screwdriver, tighten to a torque of 10 Ncm.




Platform		RP	MGIU-99

XL healing screw

used for conditioning and healing of the gums for subsequent insertion of the final prosthesis in posterior areas.

Using a 1.26 mm hexagon screwdriver, tighten to a torque of 10 Ncm.



Platform		RP	H			
			1	2	3	4
			MGIU-XL1	MGIU-XL2	MGIU-XL3	MGIU-XL4

INSTRUMENT CLEANING AND MAINTENANCE

	PROCESS	PROCESS STEP	Description, instructions, warnings
1	Initial treatment at the point of use	1.1 Soaking	The instrument should be soaked within a maximum of 2 hours after use. Use products with a proven enzyme component (e.g. DGHM, FDA, or CE marking/approval) that are suitable for disinfecting compatible instruments. Use the disinfectant according to the manufacturer's instructions. Use a synthetic cloth or soft brush to initially remove any dirt residues. Rinse the instrument under running water. WARNING: the disinfectant used for soaking is only for the protection of persons, and is not intended to replace the subsequent cleaning and disinfection steps
		1.2 Containment and transport	No special requirements. It is recommended to process the instruments as soon as reasonably possible after use and soaking.
2	Preparation prior to cleaning	-	No special requirements
3	Automated cleaning, disinfection, and drying	Thermal	It is recommended to clean the instruments using a mechanical washer-disinfector (washing, disinfecting, and drying machine). IML SA recommends using neutral or slightly alkaline detergents, free of any critical substances (depending on the concentration). The use of alkaline cleaning agents (pH 9.5 - 11.5) could cause the metal surfaces to become discoloured. However, this will not compromise the instruments' functionality. Avoid strong alkaline detergents (pH > 11.5). The products' suitability for effective mechanical cleaning and disinfection (93°C, 10 min.) using an alkaline detergent and an added surfactant agent has been verified. The manufacturer shall bear no responsibility for the use of other (or non-equivalent) detergents. Only use detergents that are proven to be effective and comparable to those indicated in this section. When choosing the cleaning system, make sure: <ul style="list-style-type: none"> • that the operating principle is suitable for cleaning instruments; • that the chemical agents are compatible with the instruments. Always respect the concentrations and action times specified by the detergent's manufacturer. Immerse the unloaded instrument, with the lid open, inside the cleaning and disinfection unit, and follow the manufacturer's instructions.
4	Manual cleaning and disinfection		It is recommended to use products with enzyme and disinfectant components. Use the product according to the manufacturer's instructions. Immerse the instrument with the lid open downwards in the ultrasonic bath solution, and use a soft brush to remove any residues remaining from the procedure. Rinse the instrument under running water after the treatment. Check its cleanliness and, if any dirt and/or foreign material is still visible, repeat the procedure.
5	Manual drying		Dry the instrument thoroughly with alcohol-based disposable disinfectant wipes or a sterile, lint-free cloth and, if necessary, using compressed air. The air pressure must be < 3 bar in order to avoid damaging the products. It is recommended for the air used for drying to be filtered.
6	Maintenance, inspection and testing		Check the products' functionality in accordance with their instructions for use, and make sure there are no visible signs of damage. For moving or rotating parts, IML SA advises against the use of instrument oil, as certain plastics tend to expand and the oils can adversely affect the instruments' proper functionality
7	Packaging		Prior to sterilisation, the instrument must be placed in a sterilisable single-use medical grade package (single or double packaging) and/or a suitable sterilisation container that is: <ul style="list-style-type: none"> # compliant with EN 868/ ISO 11607; # suitable for steam sterilisation (temperature resistance up to 134°C, sufficient steam permeability); # regularly maintained (sterilisation container) CAUTION: do not sterilise the instrument inside its original packaging used for transport.

8	Sterilisation	In a steam autoclave (Vacuum cycle at 134°C for 4 min.)	<p>For sterilisation, use only the procedures indicated below; do not use any other type of procedure.</p> <p>Steam sterilisation, check that:</p> <ul style="list-style-type: none"> # the steam steriliser (vacuum type) is compliant with EN 13060 and EN 285 # the procedure has been approved according to ISO 17665 # there is a max. sterilisation temperature of 134°C (plus tolerance according to ISO 17665) # sterilisation time: 4 minutes at 134°C. <p>The products' suitability for effective sterilisation with the aforementioned sterilisation times and temperatures has been verified. Do not use hot air sterilisation.</p>
9	Preservation		Once sterilised, the products should be stored in a cool, dry and clean place, and kept in the same packaging use for sterilisation.
10	Inspection and functionality testing		Prior to each application, carry out a visual check and a functionality test according to the operating instructions.

GUIDED SURGERY

Proper planning of surgical treatment, based on data collection through analysis, models, and radiological images, is the most important principle for successful implant therapy.

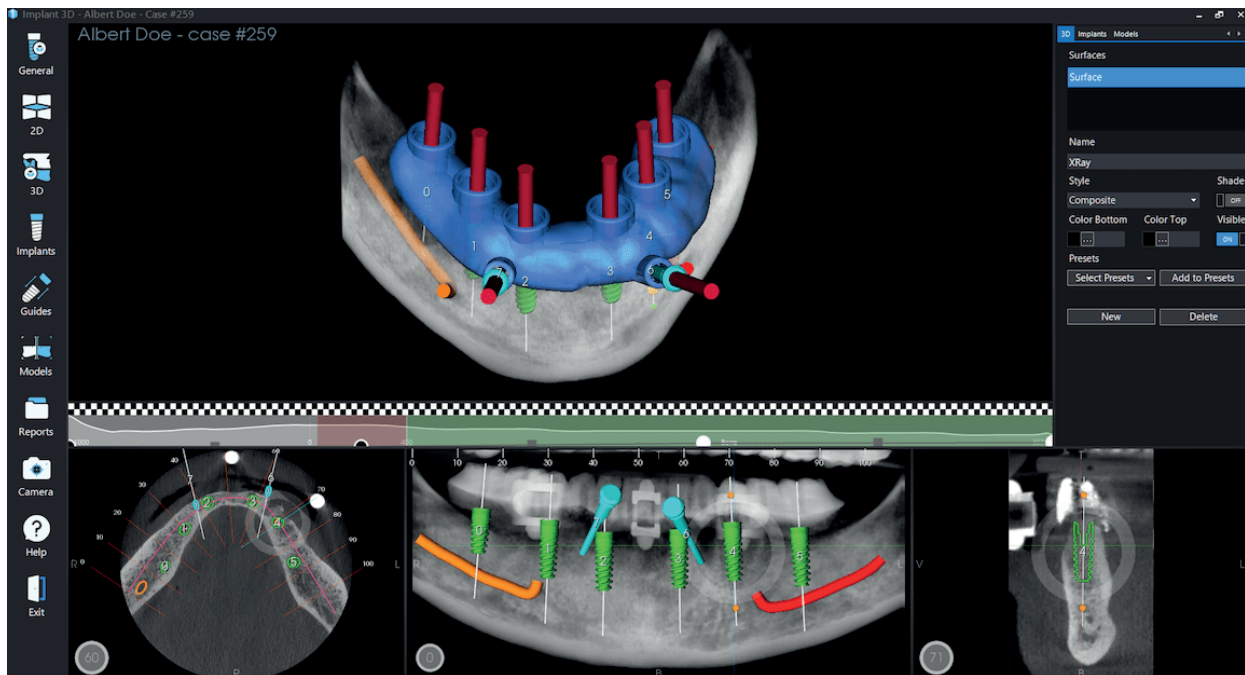
Unfortunately, there is often little correspondence between the prepared plan and the actual anatomy at the intra-operative level. In order to remedy this problem, software programmes have been developed in recent years that are able to create three-dimensional models, upon which the practitioner can perform virtual surgery under ideal conditions. On this basis, the programme is able to create surgical guides that are perfectly in line with the treatment plan.

IML is a distributor of RealGUIDE Software, developed by the company 3DIEMME, and MediaLab.



Guided surgery is an implant treatment technique that includes the steps of diagnosis, planning, and placement.

The main advantage is that the procedure can be planned working with complete 3D views of the patients' radiological and prosthetic anatomy, thus allowing for the size and final position of the dental implant to be accurately assessed, even based on the prosthetic study (wax-up), using templates for the surgical phase that can help guide implant placement based on this planning.



The IML surgical kit, BOX-CG, has been designed and developed to provide the possibility of preparing surgical sites using the guided implantology technique for the UNIVERSE, UNIVERSE 2.9, Starfly, Itros-N, and Infinity implants manufactured by IML SA.

The kit and the surgical instrumentation it contains have been designed to ensure compatibility with the main guided implantology techniques (three-dimensional diagnostic software and surgical guide templates) currently available on the market (Real Guide, Model guide, exoplan, Planmeca, etc.).

In guided surgery, there is a fixed relationship between the instruments involved, which allows for implant placement consistent with the planning. The ratio according to which the IML system has been designed is 9.00 mm between the level of the instrument stop on the bushing, the metallic cylinder inserted into the

surgical template (which serves to guide the axis of the instruments' insertion and to stop them at a certain depth), and the plane of the implant connection, or the margin between the transmucosal collar and the treatment of the endosseous body.

When adopting a surgical protocol involving an implant platform placement other than iuxtaosseous, the digital planning will automatically calculate the position of the upper margin of the bushing at exactly 9.00 mm from the plane of the connection.

In some cases, the thickness of the soft tissue may interfere with the ideal position of the flap, so it will be necessary to open the flap instead of adopting a flapless approach (A).

The possibility of also managing the submerged positioning of the implants directly via software and in perfect safety is particularly useful.

GENERAL INDICATIONS

The surgical instruments for implant systems manufactured by IML SA are reusable medical devices intended for temporary use within the oral cavity (continuous duration not exceeding 60 minutes). The surgical instruments are designed for the preparation of the implant sites, the insertion of the implants into the sites, the tightening and unscrewing of all the connecting screws (surgical cover screws, transmucosal healing screws, abutment screws, prosthetic screws, impression coping screws, etc.).

The surgical instruments are intended for use with dental implants manufactured by IML SA.

The use of the surgical instruments for procedures involving implants other than those manufactured by IML SA will limit the liability borne by the manufacturer and will void the product warranty. The company shall bear no liability for the use of non-original equipment.

IML SA surgical instruments are sold in NON-STERILE packaging. They must be cleaned, disinfected, and sterilised prior to use in accordance with the relative instructions. Failure to comply with this warning could result in patient infections.

The materials used to manufacture IML SA surgical instruments have been selected based on the properties indicated for their intended use, in accordance with Directive 93/42 implemented in Italy by Law no. 46/97, Annex I Essential Requirements, point 7.1, and European Regulation 2017/745. The relative code, content description, and batch number are indicated on each package. These same data, which are also indicated on the labels inside the packaging, must always be cited by the doctor for any relevant communications. Most of the devices are identified by laser markings that allow the device to be uniquely identified (e.g. diameter or length). In order to ensure protection against bacterial contamination, it is recommended to always use surgical gloves when handling the devices, both during use and during cleaning and sterilisation. The failure to observe these rules could lead to cross-infection.

SURGICAL KIT

The surgical kit has been designed and manufactured to ensure ease of use and an immediate understanding of the sequence of instruments. The instruments are all made of surgical steel, and have descriptions screen-printed on the tray in order to allow the user to more easily identify each one, as well as to facilitate subsequent repositioning after cleaning and disinfection, thanks to a colour-coded system indicating the appropriate surgical procedures for the various implant diameters.

The kit includes housings for all the instruments for the preparation of short implants up to 6.00 mm in height, and long implants up to 15.00 mm, with a maximum implant diameter of 4.6 mm.

Important warning:

The kit and the surgical instruments it contains are sold in NON-STERILE packaging.

They must be cleaned, disinfected, and sterilised prior to use.

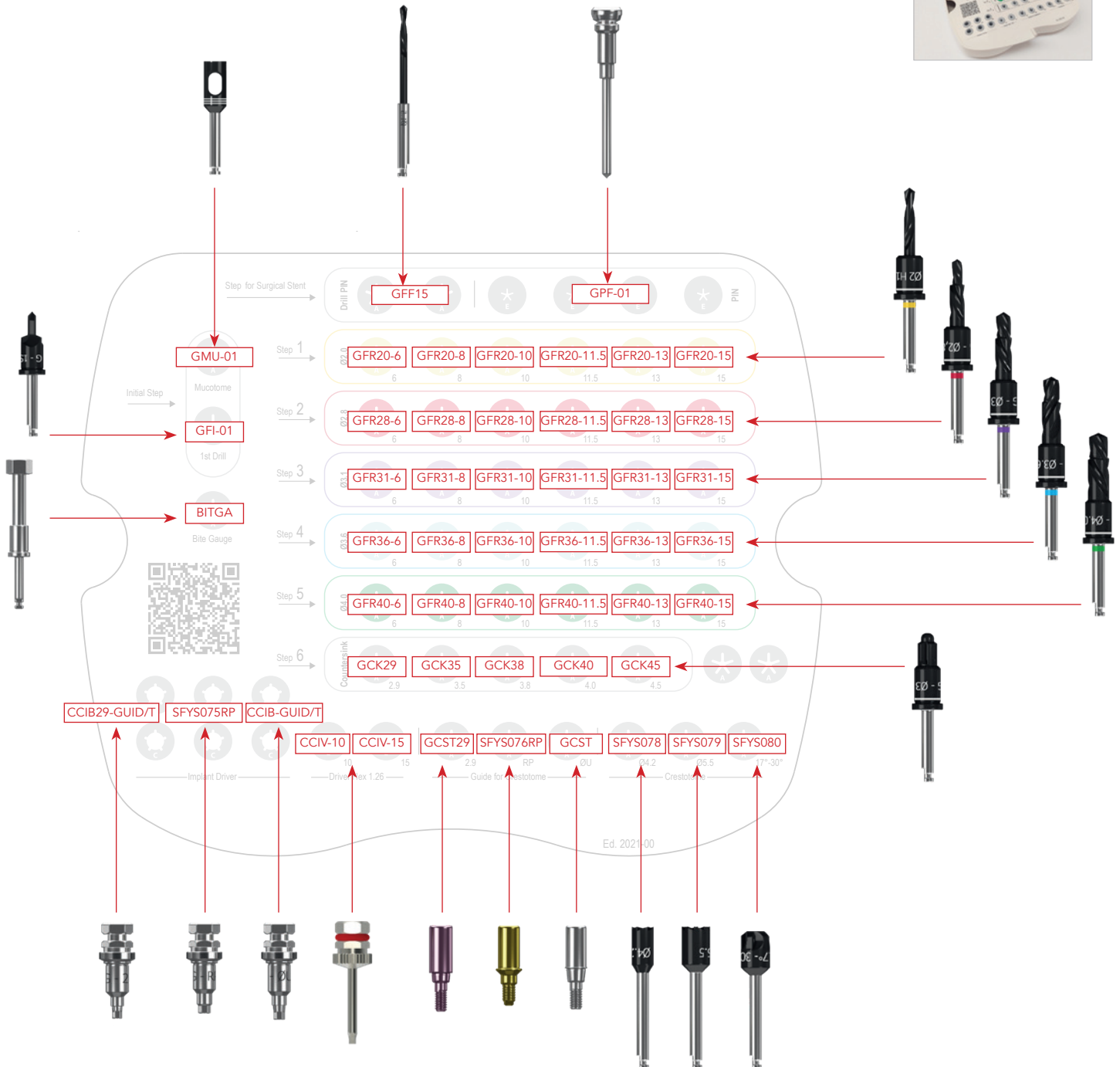
Failure to comply with this warning could result in patient infections.

GUIDED SURGERY KIT

NOTES:

Pay attention to the instruments' direction of insertion, as shown in the pictures

BOX-CG



* THE RATCHET IS FOUND BELOW THE TRAY



ROTARY INSTRUMENTS

All IML SA drills are made of surgical steel with a high degree of resistance to corrosion and wear. They are intended for surgical use, meaning that they have a shank with a contra-angle handpiece attachment, and must be used with a suitable micromotor. Their extremely accurate design and construction allow for vibration and oscillation-free operation. However, the incorrect insertion of instruments into the handpieces can lead to instrument vibration, eccentric rotation, premature wear, and bending of the shank.

It is recommended to only utilise surgical micromotors suitable for the intended use. It is recommended to have the micromotors periodically checked by their manufacturers, in accordance with the manufacturers' instructions, in order to prevent any possible malfunctions (e.g. axis displacement of drive shafts, worn or malfunctioning grippers, etc.).

Failure to follow the instructions provided could lead to surgical complications and consequent health repercussions for the patient. In order to avoid the possibility of bone necrosis, it is recommended to use the rotation speeds indicated in the following procedures. Lever-type movements increase the risk of instrument fracture, and should therefore be avoided. Abrupt changes in speed should generally be avoided. Never apply pressure to the point of forcibly stopping the instrument's rotation. This could lead to excessive heat build-up in the tissues being cut, resulting in bone necrosis, and could damage both the instrument and the device being utilised (micromotor).

This could also lead to the breakage of the instrument itself. It is also recommended to work intermittently, with a to-and-fro vertical motion, in order to avoid overheating and wear on the working part, and undue heat build-up in the tissues being cut. The use of an appropriate liquid coolant is recommended. Lack of adequate irrigation can lead to bone necrosis. Drill wear is largely dependent on the type and density of the bone being milled: harder bone results in increased wear on the instruments.

In order to ensure greater safety and caution with respect to the wear resistance capacity of the device, it is recommended that the drills be used for no more than 200 cycles, or less if the tools are losing their cutting capacity. It is recommended to check the maintenance status and remaining cutting capacity after each procedure. IML SA shall bear no liability for excessive use.

Never use damaged, bent or worn instruments.

The guided surgery drills are designed to be used inside the drill stops manufactured by IML SA, and inserted into the surgical templates by the respective manufacturer.

IML SA shall bear no liability for any malfunctions or damage due to the use of guided surgery drills with non-original drill stops or drill stops that are not compatible with the dimensions of the instruments, which could get stuck, may not be guided correctly, or could result in a placement different from that planned by the clinician if the bushing's height is incorrect.

TOOL AND ACCESSORY DESCRIPTIONS



BITE GAUGE (BITGA)

This mouth aperture gauge simulates the maximum length of the drills contained in the Guided Surgery Kit via a graduated scale, and should be used prior to CT/CBCT examination of the patient. The size of the hexagon at the base of the instrument reproduces the size of the hexagon of the guide cannula embedded in the resin of the surgical guide.



GUIDE Drill stops

The guide drill stops are red anodised titanium cylinders (GBG50) that are embedded in the polymer of the surgical template to guide the rotating instruments during preparation, so that they maintain the working axis programmed with the planning software, and provide a physical stop at approximately 9.00 mm from the plane of the implant connection platform for all the instruments. IML manufactures the indexed drill stops with an upper hexagon, which allows the positioning of the implant connection planned in advance with special software to be respected.



MUCOTOME – GMU-01

This instrument performs a 4.9 mm diameter mucotomy prior to the passage of the drills in flapless surgical procedures. In the case of a small amount of keratinised gingiva, it is recommended not to use the mucotome, and to make a flap at the implant site instead.

Made from hardened DLC-coated surgical steel, this mucotome has special notches 1 mm apart that help the surgeon determine the height of the soft tissue.



DRILLS FOR RETAINING PINS – GFF15

Made from hardened DLC-coated surgical steel, the drill for the retaining pin is sharp at the tip and atraumatic at the edges. The drill must pass all the way through the cannula to ensure optimal pin retention.



RETAINING PIN – GPF-01

The retaining pin secures the surgical guide in place. The pin must be pushed all the way in.



INITIAL DRILL – GFI-01

The initial drill made of hardened, DLC-coated surgical steel removes the mucous rim and prepares the cortical bone for the passage of the first drill. The initial drill is inserted as far as it will go through the surgical guide.



DEPTH DRILLS – (GFR DRILL SERIES)

The depth drills made from hardened DLC-coated surgical steel handle the initial preparation of the implant site (2.0 mm diameter) for the following implant lengths: 6 - 8 - 10 - 11.5 - 13 - 15 mm. The notch visible on the guide cylinder is 1 mm away from the stop, and provides a visual indication in case a reduced osteotomy height is to be realised.

All of the drills are colour-coded with a ring, which allows for the easy identification of the drill diameter.



COUNTERSINK (GCK SERIES)

The countersinks complete the preparation of the implant site, managed based on the implant and the bone density.

The notch visible on the guide cylinder is 1 mm away from the stop, and provides a visual indication in case a reduced osteotomy height is to be realised.



IMPLANT DRIVER – CCIB29-GUID/T -SFYS075RP – CCIB-GUID/T (series)

The implant driver connects to the implant via the retaining screw, and guides the implant's direction and depth via the surgical guide. Thanks to the hexagonal reference on the implant driver, it is also possible to check the position of the implant connection via the surgical guide.

NOTE: they are available for the CC NP, CC RP, HEX RP platform.

The implant drivers supplied in the surgical kit are made from grade 5 medical titanium. A surgical stainless steel version is also available in stock, which offers greater durability.

Connections with the same characteristics, but without the connection screw, will soon be available, and will work directly on the implant connection, reducing the problems associated with the screw loosening.



CRESTOME Ø4.2 / Ø5.5 (SFYS078 - SFYS079 are cylindrical)
Used to remove residual crestal bone for the correct positioning of straight MUAs and abutments.
To be used AFTER the removal of the surgical guide.
CRESTOTOME 17-30° (SFYS080 is conical)
To be used AFTER the cylindrical crestotome for the correct positioning of angled MUAs and abutments.



GUIDED PROTECTION SCREWS FOR CRESTOTOME (GCST29 - SFYS076RP - GCST)

Connect the protection screw directly to the implant and proceed with the guided removal of the excess bone portions using the bone drills.
They are anodised based on the platform:
pink CC NP
grey CC RP
yellow HEX RP

NOTE: they are available for the CC NP, CC RP, HEX RP platform.



DRIVERS

The manual drivers are designed to be used to connect the guided crestotome protection screws and the connection screws contained in the implant driver. The drivers are 1.26 hexagonal and are compatible with all the screws in the IML range



TORQUE RATCHET (DN-I)

The Torque Ratchet is used for the manual phase of implant insertion. Make sure that the flat face of the hexagon on the fitter lines up with the flat face of the hexagon on the guide cannula head, in accordance with the implant's virtual planning.

Thanks to the capabilities of the Guided Surgery system, the doctor will determine the exact position, diameter, and height of the implant to be inserted. The correct positioning is determined by the practitioner, based on his or her clinical experience, and the accuracy of the chosen software. The IML SA kit can be used with any software that respects a fixed instrument stop distance of 9.00 mm from the implant platform.

PREPARATION FOR THE GUIDED SURGERY

NOTE: each software has its own features and workflow for generating the surgical template and the implant and prosthetic planning.

The following is a list of main general procedures for properly preparing the planning and the surgical instruments.

IMPRESSION AND PLASTER MODELS

In-office impressions can be taken with either standard trays or special trays for edentulous patients.

The certified laboratory uses the precision impression to create the Master model in plaster, eliminating the strong undercuts up to the fornices.

This model must be duplicated to obtain one without any undercuts.

In the case of post-extractions, the undercuts must be managed considering that the surgical guide will rest on the mucosa.

The digital process involves the use of an intraoral scanner to improve accuracy and patient comfort.

Digital impressions can only be taken in cases of partial edentulism, with the aim of obtaining an adequate oral survey of the soft tissue and the tooth surfaces.

The Universal Stent should not be used during intraoral acquisition.

CREATION OF THE RADIOGRAPHIC TEMPLATE

The creation of the radiographic template is required for patients with total or extensive edentulism.

The radiographic template must meet the construction specifications determined by the technicians during the certification course, and must meet the specifications indicated on the implementation checklist.

For cases in which the patient has an appropriate removable prosthesis or one that needs to be relined, a double scan is carried out, and no radiographic template is required.

OPTICAL SCANS

If the radiographic template has been created, the following scans must be performed:

- Plaster model with radiographic template
- Plaster model only, maintaining the same coordinate system

For cases that fall under the ModelGuide Easy protocol, the scanning of the plaster model alone is sufficient. If the office has an intraoral scanner, the STL file for the arch concerned is sufficient.

CT SCAN

The patient must be sent to the radiology centre with the relative registration material and an appropriate prescription containing the instructions for the radiologist.

In cases falling under the double scan protocol, the following CT scans are required:

- Acquisition – Patient with prosthesis

Note: The double scan protocol can also be done by placing radio-opaque indicators directly on the flanges, although this will drastically reduce the accuracy of the software coupling.

MATCHING

After having imported the Dicom of the CT examination into the software, the STLs must be registered based on the type of protocol before the implant planning can be carried out.

Protocol with plaster model

- CT - STL (model + radiological) Digital protocol
- CT - STL arch (in the case of intra-oral scanning or ModelGuide Easy cases) Double scan protocol
- CT scan (patient + prosthesis) – CT scan (prosthesis)

SOFTWARE DESIGN

After having performed the coupling, the virtual planning is carried out with Implant 3D software or derivatives.

Once the design has been completed, it is possible to move on to the creation of the surgical guide.

CREATION OF THE SURGICAL GUIDE

With the implant planning completed, we now move on to the creation of the surgical template for the guided implant-prosthetic procedure.

The surgical procedure performed with the instruments illustrated above is described below. In order to preserve the bone, it is important to thoroughly irrigate the surgical site during the surgical procedures.

IMPLANT SURGERY

- Anaesthesia
- Positioning and fixing of the surgical guide
- Mucotomy
- Initial preparation
- Depth preparation
- Placement of the implant
- Removal of guide and fixing systems

ANESTHESIA

It is recommended to avoid allowing anaesthetic to infiltrate into the keratinised mucosa in order to prevent possible dimensional variations, which could compromise the precision with which the surgical template is positioned. Therefore, in the maxilla it is recommended for plexic anaesthesia to be performed in the vestibular fornix, with a truncal block at the level of the greater palatine foramen and the nasopalatine foramen, while in the mandibular region it is recommended for plexic anaesthesia (or possibly truncular anaesthesia at the inferior alveolar nerve) to be performed, with infiltration at the level of the lingual floor.

POSITIONING OF THE SURGICAL GUIDE

Position the surgical guide, making sure that it is stable. In the case of a surgical guide with a retaining pin, interpose the silicone occlusal splint between the arches and have the patient occlude the surgical guide during the retention phase.

USE PARTICULAR CAUTION DURING THIS PHASE, AS THE INCORRECT POSITIONING OF THE GUIDE CAN JEOPARDISE THE ENTIRE SURGICAL PROCEDURE.

IMPORTANT:

When it is not possible to stabilise the surgical template on the remaining teeth, a full-thickness flap protocol should be adopted to ensure bone support. Since an edentulous arch would still result in tilting, it is necessary to stabilise the template with the retaining pins included in the kit.

In order to prepare the housing for the pins, the corresponding drill is supplied, to be used at 800 rpm.

FIXING THE SURGICAL GUIDE

Insert the retaining pin drill (GFF15) into the vestibular cannulae, press until contact with the bone is felt and activate the motor by pressing on the handpiece until it reaches the end of its stroke. Extract the drill and insert the retaining pin (GPF-01). Repeat the operation for all the retaining pins. Check the guide's stability before proceeding with the other steps.

The preparation must begin with the use of two surgical accessories contained in the kit, namely the mucotome and the initial drill.

MUCOTOMY

Remove the occlusal splint and perform the mucotomy by inserting the appropriate instrument (GMU-01) through the cannulae of the surgical guide until the mucotome makes contact with the bone crest. It is possible to remove the soft-tissue portion through the cannula with a special dissector, or else to remove the template and access the gingiva directly, repositioning it at the end of the mucotomy using the silicone splint again.

The mucotome creates a slight over-preparation of the mucosa in order to avoid direct contact with the drills

INITIAL PREPARATION

Insert the initial drill (GFI-01) through the guide cannula with the MOTOR STOPPED until the tip makes contact with the bone, simultaneously checking that the cylindrical part of the drill has engaged in the guide cannula, then start the drilling phase at low speed (800 rpm). Use particular caution when inserting the tip of this drill (perfectly aligned with the guide cannula), as it is responsible for the subsequent drills' general direction of insertion. Make sure that the mucous annulet has been completely removed prior to drilling the implant site, and irrigate thoroughly to ensure the absence of any mucous tissue within the implant site.

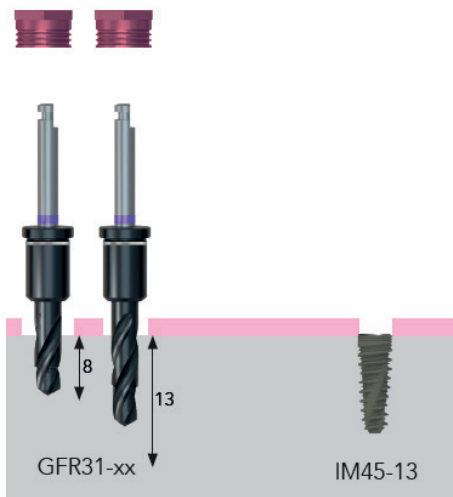
Thanks to its morphology, the drill allows for the creation of a hole with a diameter of \varnothing 2.00 mm and a depth of 4.50 mm (A). This means that the end drills that will be used later will be guided during the first few millimetres at the tip (by 4.50 mm from the hole created by the initial drill), as well as in the guide bushing. The initial drill also has cutting capacity on the oblique profile at the end of the portion that is guided in the bushing, in order to eliminate the irregularities in the bone crest.

DEPTH PREPARATION

Start the implant site preparation procedure by inserting the first 8 mm depth drill (MANDATORY) through the guide cannula with the MOTOR STOPPED until the tip makes contact with the bone, simultaneously checking that the cylindrical part of the drill has engaged in the guide cannula, then start the drilling phase at low speed (800 rpm).

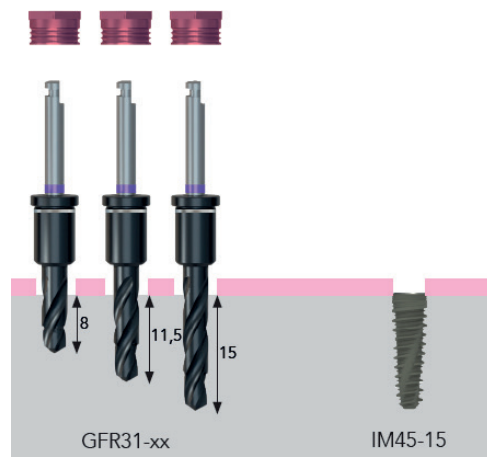
Depending on the length of the implant to be inserted, proceed with the next depth drill, based on the diagram below:

- Implants up to 13 mm in length: after using the 8 mm drill (GFRXX-8 series), directly insert the drill corresponding to the length of the implant to be placed. (Figure no. 1)



(Figure no. 1)

- Implants longer than 13 mm: after using the 8 mm drill (GFRXX-8 series), insert the 11.5 mm drill (GFRXX-11.5 series) followed by the drill corresponding to the length of the implant to be placed. (Figure no. 2)



(Figure no. 2)

Proceed with bone drilling to the end of the stroke and at low speed (800 rpm), irrigating the implant site thoroughly after each drill pass to prevent the bone from overheating.

If necessary, the drill can be used directly at the final length after preparing the site with the shorter length drill. In this case, the guidance of the drill is only obtained in the osteotomy, and not in the bushing, which reduces the insertion accuracy (there may also be a slight misalignment between the drill and the bushing).

All the drills for the IML SA system are cylindrical with a helical geometry.

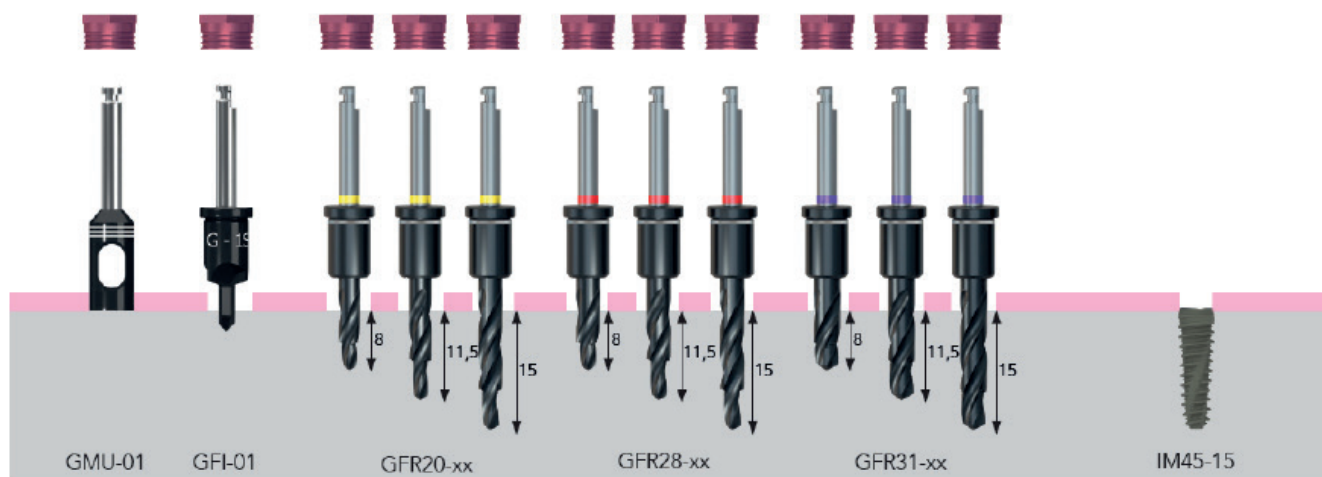
The drills up to 3.00 mm in diameter have double-lead threads, while the drills above 3.00 mm in diameter have triple-lead threads.

Each drill has a coloured band that allows for the immediate identification of the diameter being utilised. The drills have laser markings indicating their length and diameter. All the drills are electropolished and DLC-coated to ensure high wear resistance and a low coefficient of friction, thus reducing the heat generated by drill/bushing contact.

FINAL PREPARATION

Continue with the implant site preparation using the dedicated IML preparation drills (to be managed based on diameter, implant length, and bone density).

Like in the case of depth preparation, the 8 mm drill must be used first, followed by the drill that corresponds to the length of the implant to be inserted, up to 13 mm, with the 11.5 mm drill being used in between for implants longer than 13 mm. (Figure no. 3)



(Figure no. 3)

Insert the drill into the guide cannula of the surgical template with the MOTOR STOPPED until the tip of the drill enters the hole prepared in the bone by the previous drill passage. Simultaneously check that the cylindrical part of the drill has engaged in the guide cannula (DOUBLE GUIDANCE: the drill tip in the previous made hole, and the cylindrical body in the guide bushing), then start the drilling phase at low speed (800 rpm).

If necessary, the drill can be used directly at the final length after preparing the site with the shorter length drill. In this case, the guidance of the drill is only obtained in the osteotomy, and not in the bushing, which reduces the insertion accuracy (there may also be a slight misalignment between the drill and the bushing). The notch visible on the guide cylinder is 1 mm away from the stop, and provides a visual indication in case a reduced osteotomy height is to be realised.

USING THE COUNTERSINKS

If excessive friction is generated by the coronal cortical layer, the implant neck can be prepared with countersinks included in the surgical kit.

The countersinks are universal, as they carry out a cylindrical preparation designed to achieve the correct neck preparation for IML SA implants, and the countersink at the tip has a non-cutting guide.

Note. For implants of reduced height H6, it is recommended not to use countersink.

GUIDED IMPLANT PLACEMENT

Once the implant site has been created, proceed with implant placement using the specific IML implant drivers for the selected implant line, strictly adhering to the clinician's experience and the IML procedure.

Mount the dedicated implant driver on the implant (check that the connection of the driver is correct based on the implant being utilised BEFORE carrying out the procedure), and use a 1.26mm hexagonal driver (code) to tighten the connection screw to 15 Ncm).

In order to mount the implant driver, to remove the implant holder from the ampoule, remove the red safety cap, insert the implant driver into the implant, and tighten the screw.

Once this has been done, by exerting the correct pressure on the implant holder, the implant can be removed and subsequently brought to the site (thanks to this procedure, the implant is never handled and

contaminated).

Insert the implant with the implant driver pre-mounted all the way through the guide bushing using the torque ratchet (code), tightening to a maximum of torque 45 Ncm.

If any difficulties should be encountered during placement due to excessive implant insertion torque, remove the implant and prepare the site with a larger diameter drill or countersink, or with a dedicated instrument, depending on the surgical site.

In the case of bone with spongy consistency or little resistance, once the bottom has been reached, stop immediately to prevent the bone from deforming and losing the necessary stability.

When using angled abutments and MUAs, it is important that the hexagon at the head of the implant driver be aligned with the hexagonal profile of the cannula inserted into the surgical guide whose position has been planned beforehand.

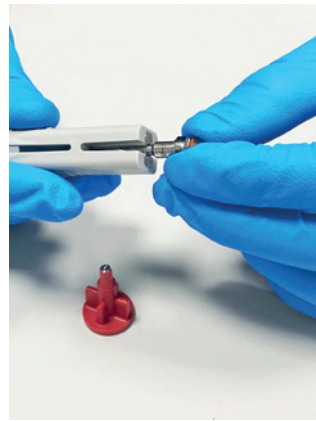
Hold the implant driver in position while moving on to the insertion of the next implant (to increase the stability of the surgical guide). In the case of multiple implants, it is recommended to insert them alternating between the right and left sites in order to avoid the risk of rotating the surgical template with respect to the centre. Keep a maximum of two or three drivers in place (depending on the number of implants to be inserted), so as not to generate excessive tension on the surgical guide

There are three implant driver versions available, which are made with different materials, and therefore offer different strength and versatility levels:

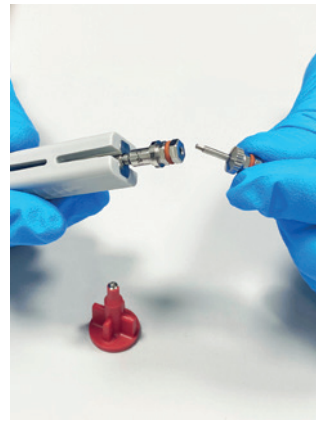
- Implant driver with medical titanium through-screw.
- Implant driver with surgical steel through-screw.
- One-piece surgical steel implant driver.



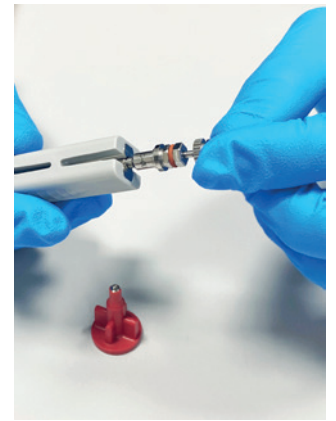
STEP 1



STEP 2



STEP 3



STEP 4



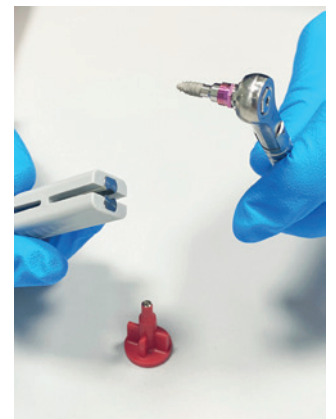
STEP 5



STEP 6



STEP 7



STEP 8

REMOVAL OF THE GUIDE

At the end of the insertion phase, disassemble the surgical guide by removing the following elements in the order listed to: the surgical guide attachment pins, the connection screws, and the inserted implant drivers. Verify the possibility of properly coupling of the prosthetic components, eliminating any excess soft tissue and residual bone ridges that may interfere with the fitting of the abutments.

For this purpose, the IML SA kit includes one set of cover screws for each implant platform (CC NP, CC RP and HEX RP), and three different types of crestotome burs.

Crestotome burs are very useful for levelling out very irregular bone ridges at the coronal level, especially for the subsequent use of MUA abutments.

There are three types:

the Ø4.2 cylindrical crestotome, which profiles the bone to create a Ø4.2 mm cylindrical space above the implant.

the Ø5.5 cylindrical crestotome, which profiles the bone to create a Ø5.2 mm cylindrical space above the implant

the 17-30° conical crestotome, which profiles the bone to create a conical space of up to Ø5.9 mm. It is indicated for the subsequent insertion of MUA Abutments.

Mount the bone mill guide and connection protection screw on the implant (make sure that the screw's connection is correct for the implant being utilised BEFORE carrying out the work), insert the crestotome with the motor stopped until it engages with the screw guide cylinder, then proceed at low speed until it reaches the end of its stroke. It is recommended to avoid exerting excessive pressure on the handpiece at the end of its stroke, and to work with an oscillating motion, in order to avoid indirectly over-tightening the protection screw, thus rendering removal from the implant difficult.

Remove the protective screw at the end of the operation

Once these operations have been completed, the prosthesis can be mounted as planned during the preoperative phase.



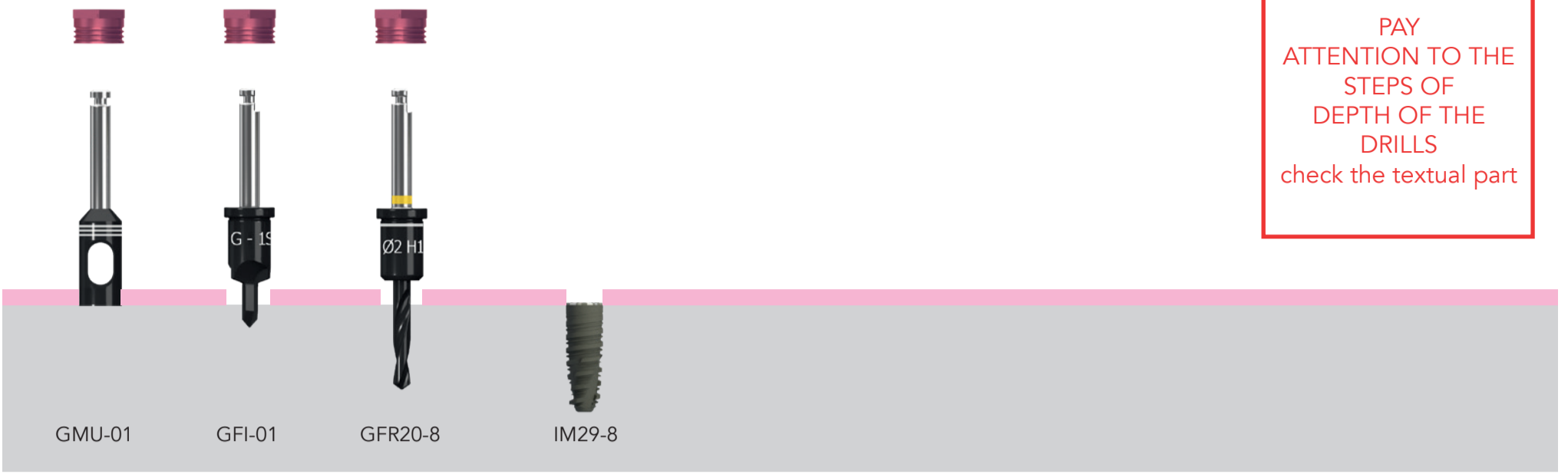
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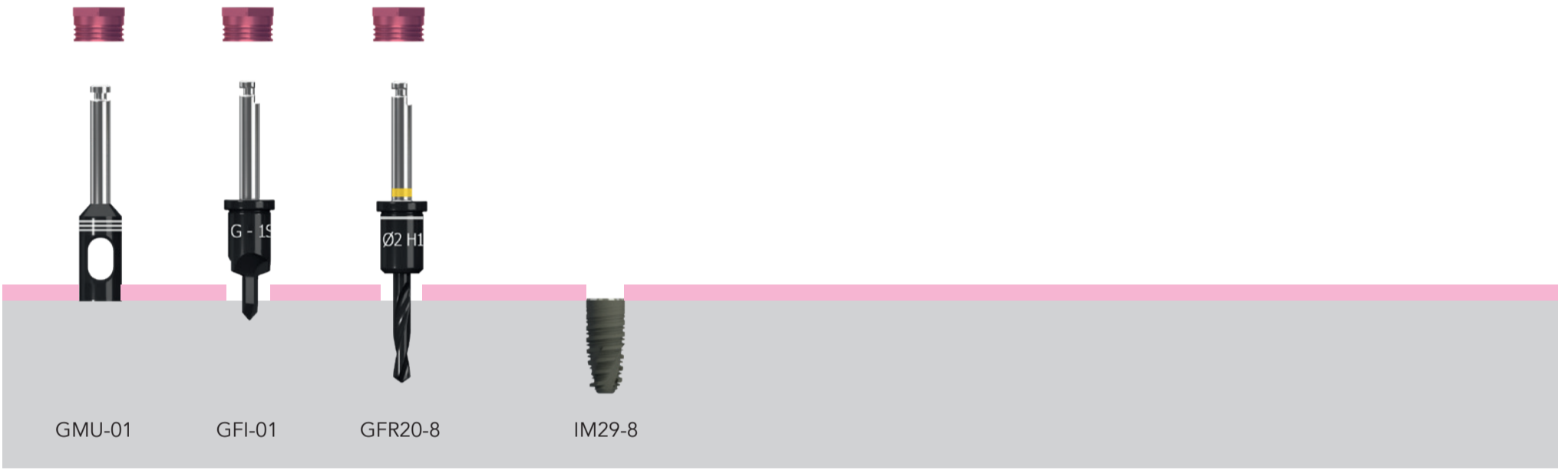
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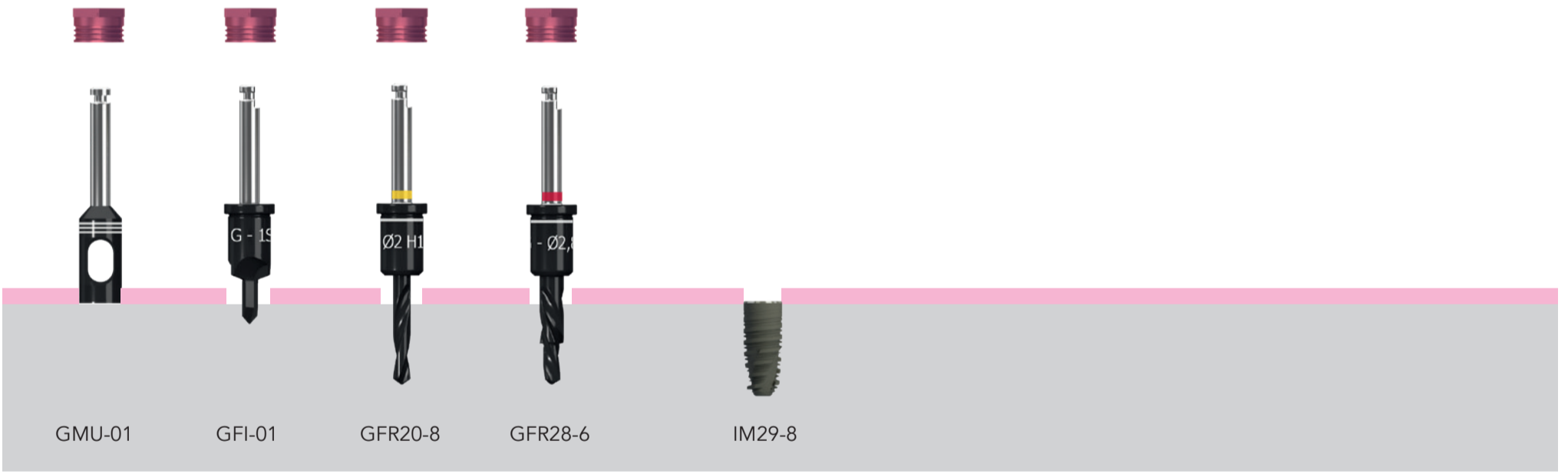
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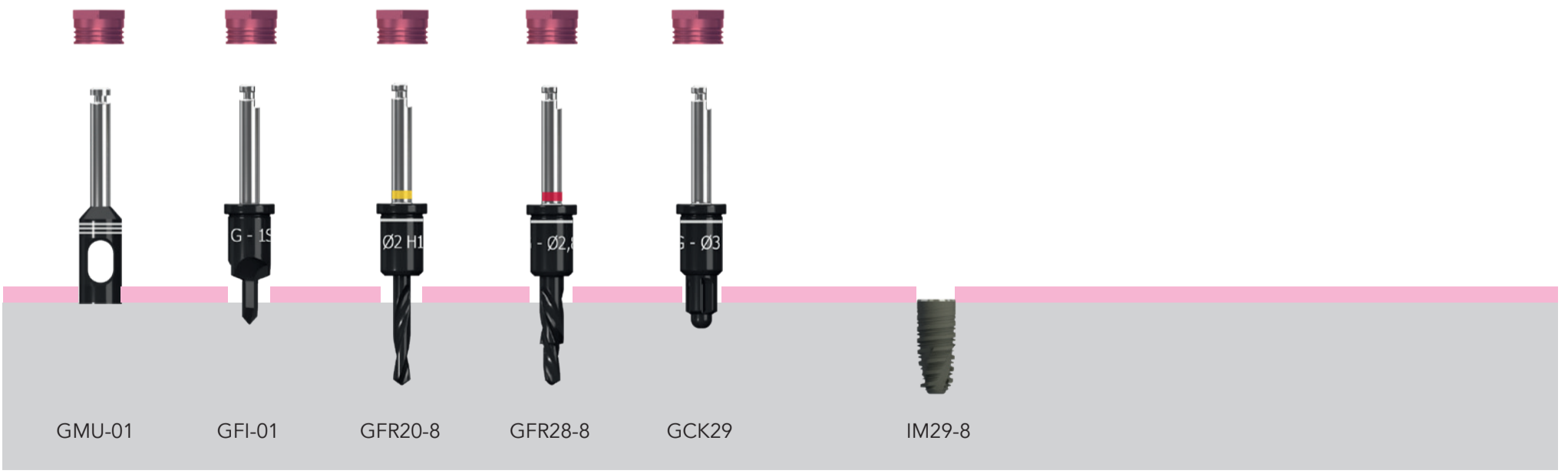
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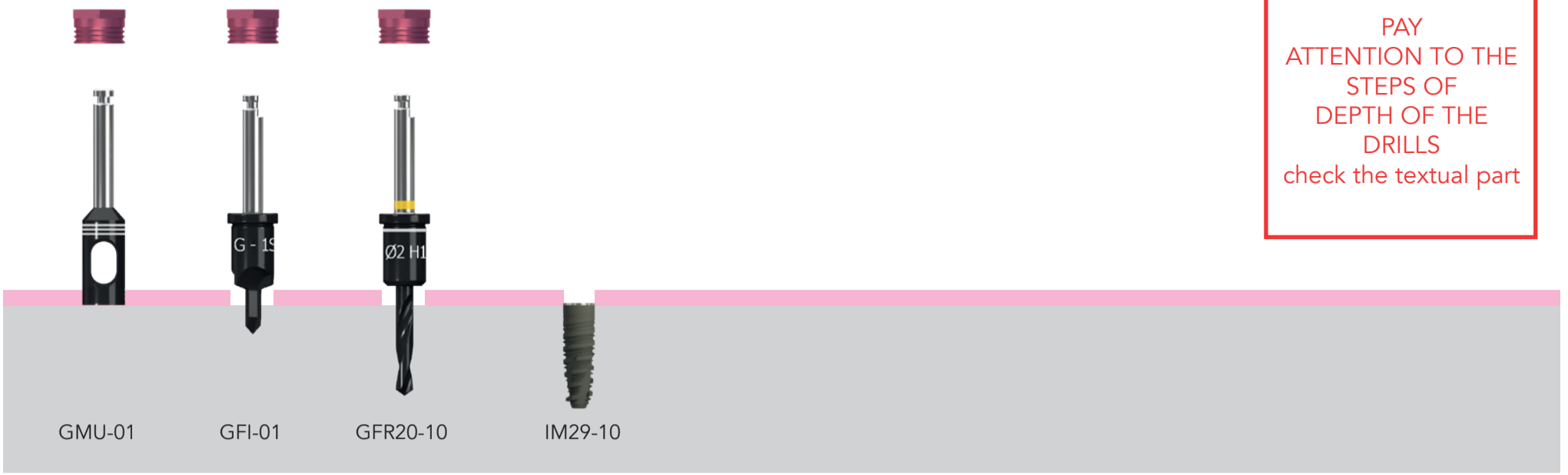


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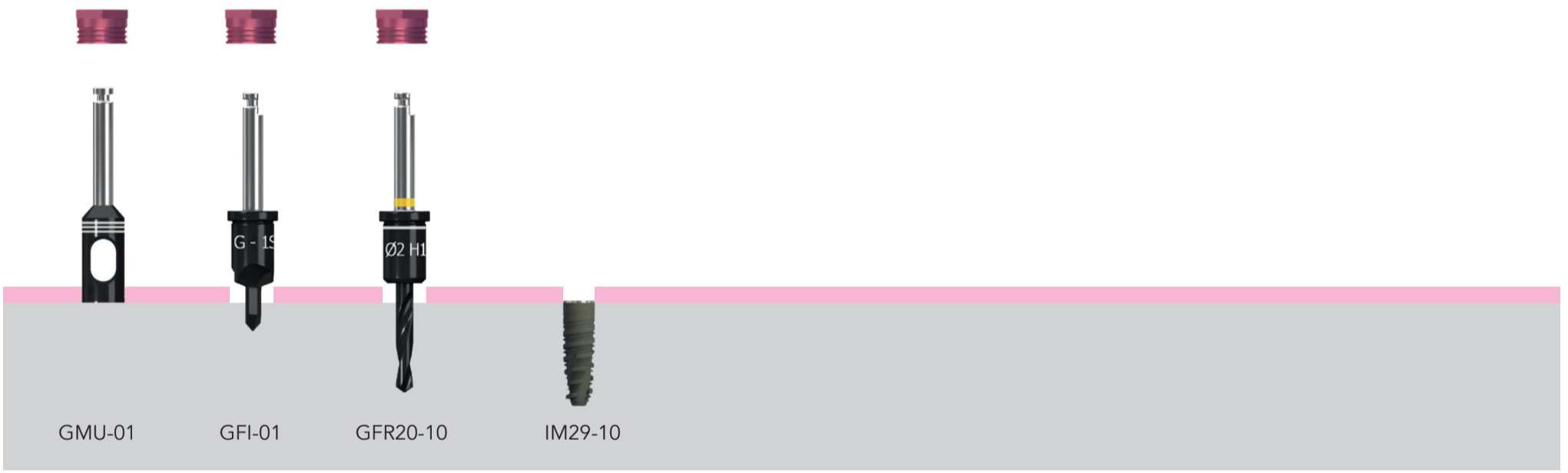


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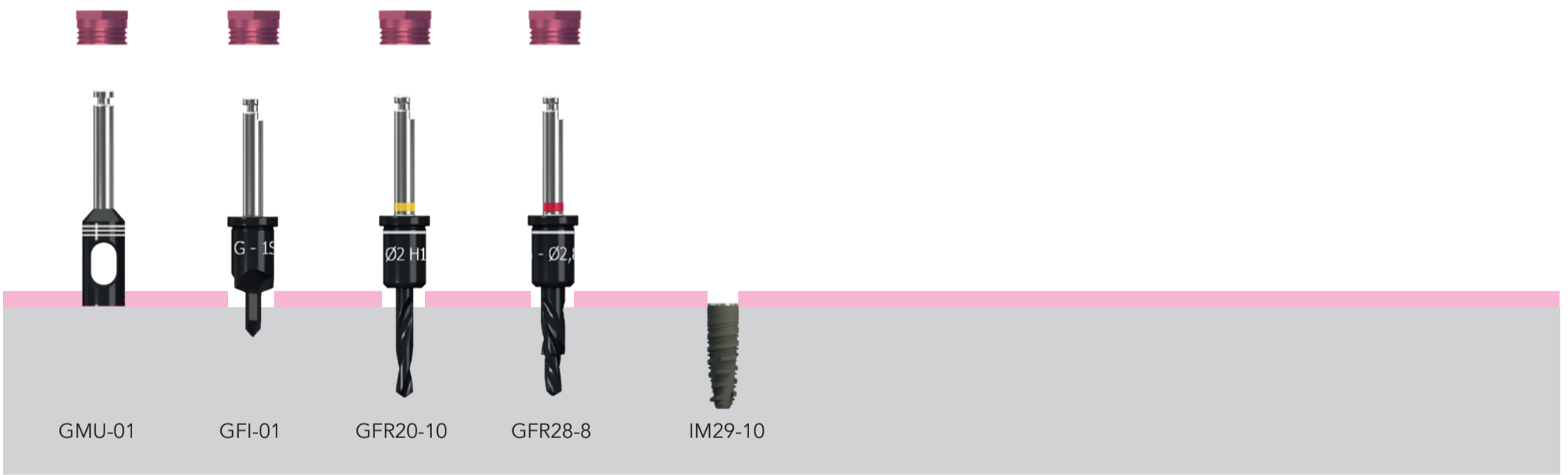
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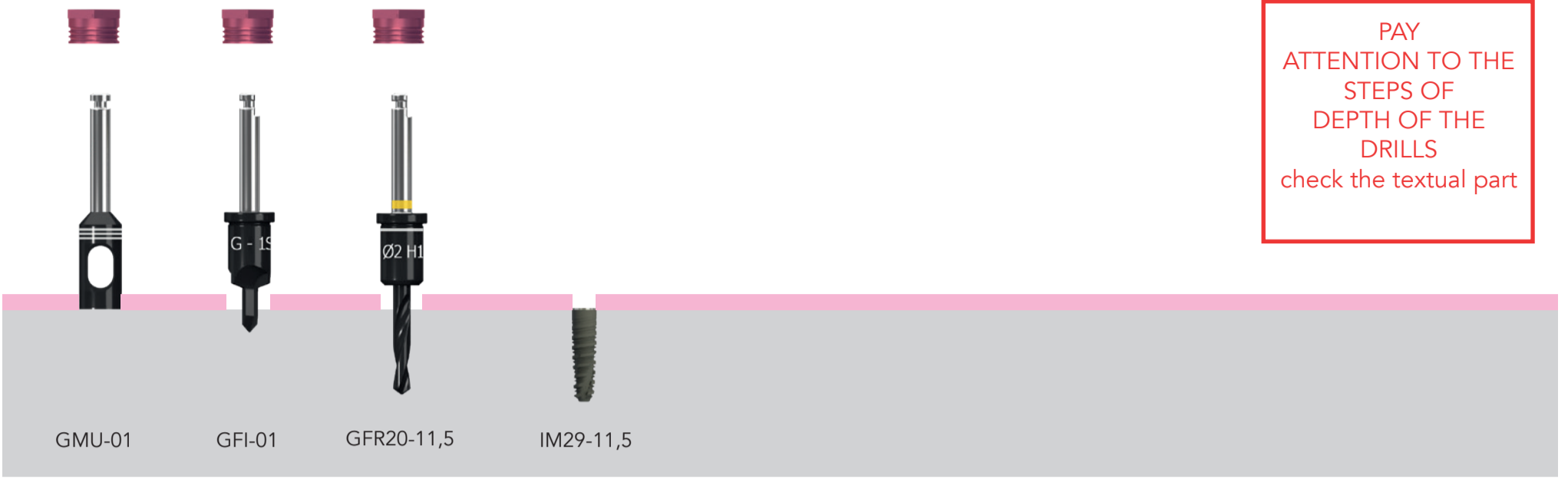


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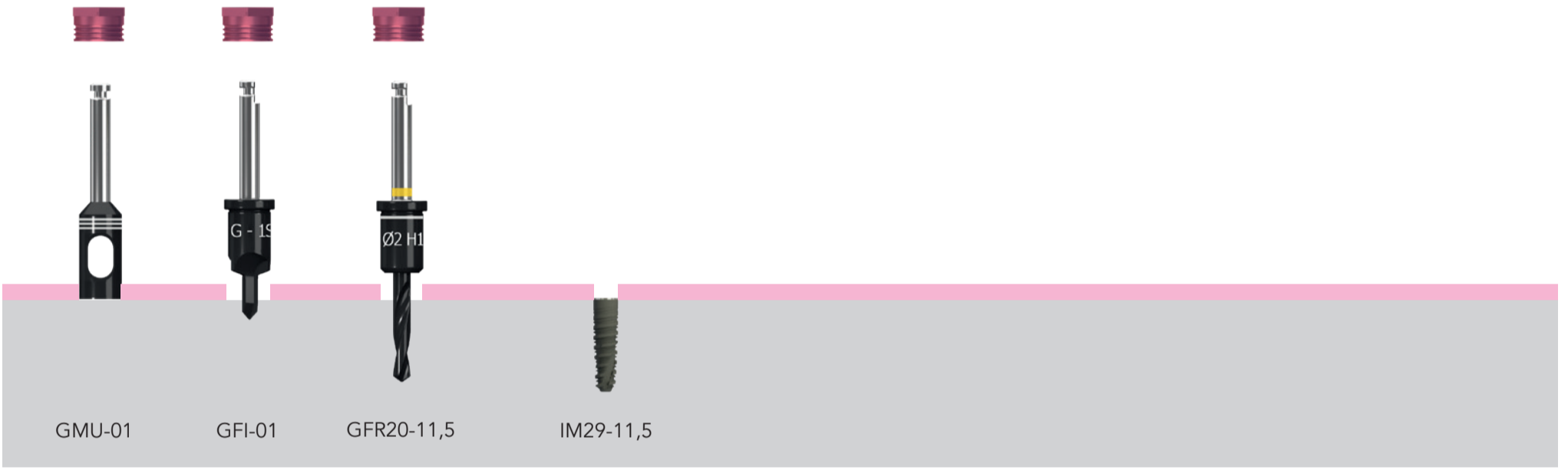


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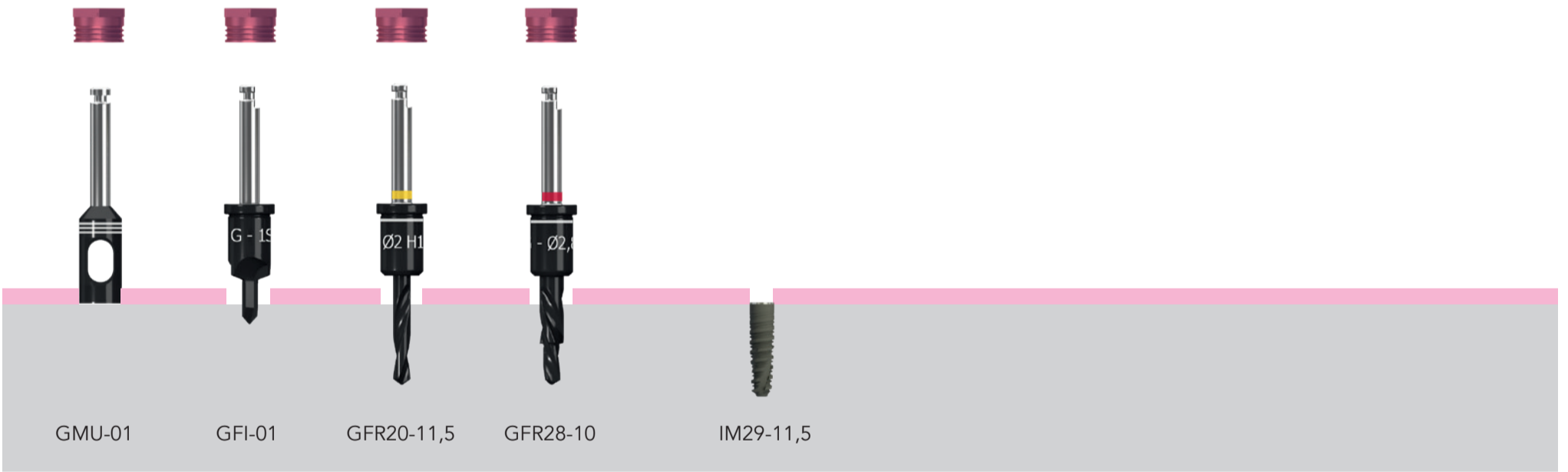
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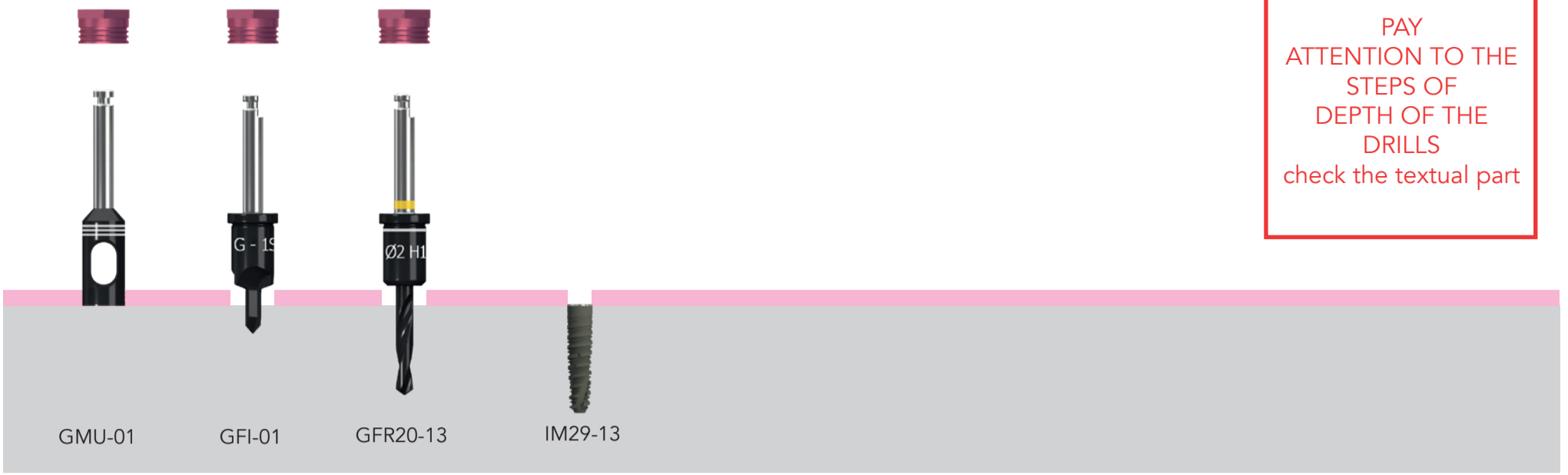


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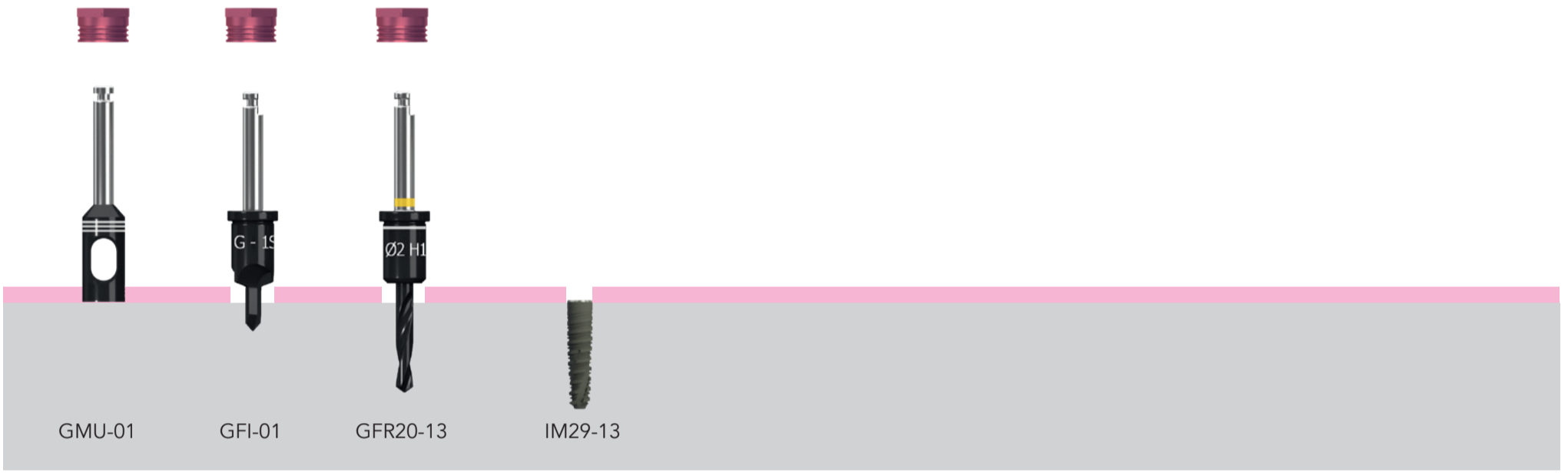


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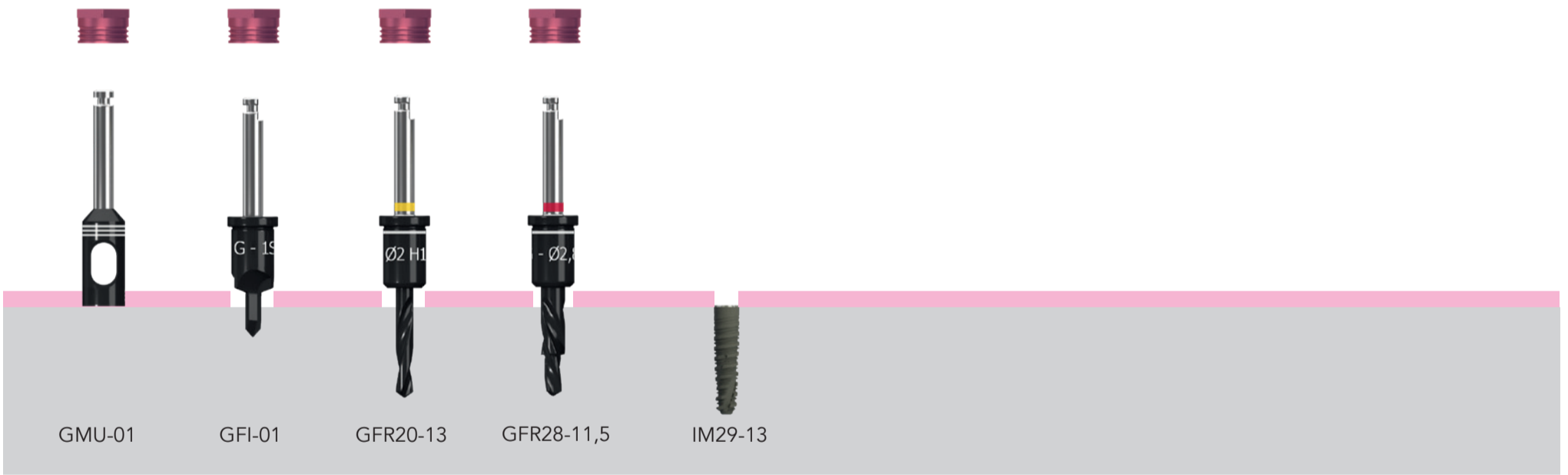
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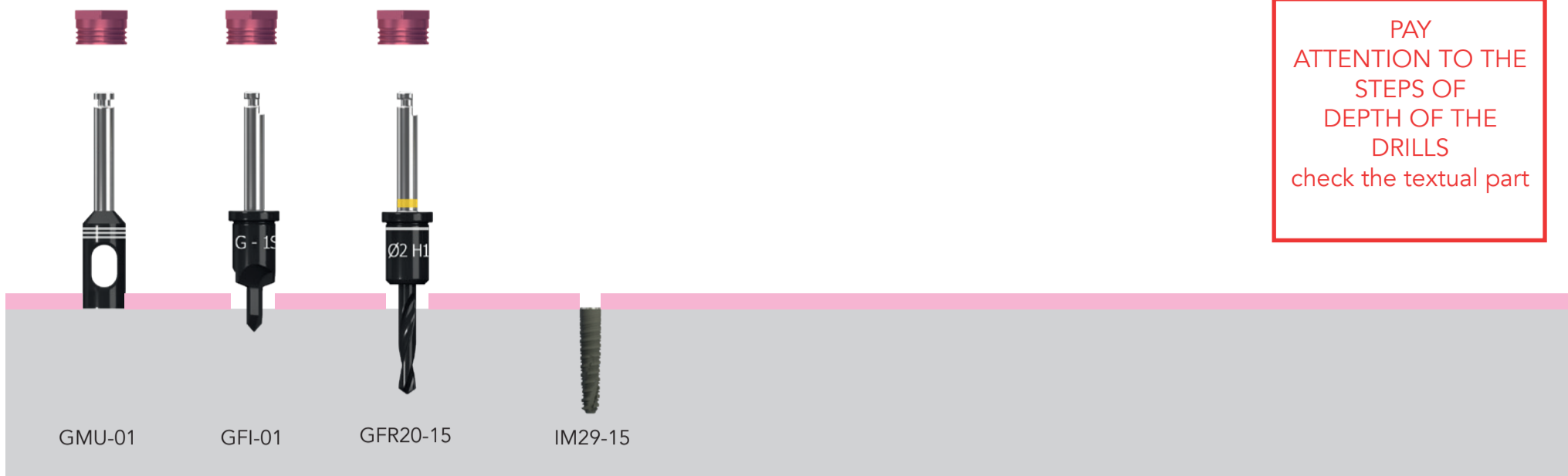


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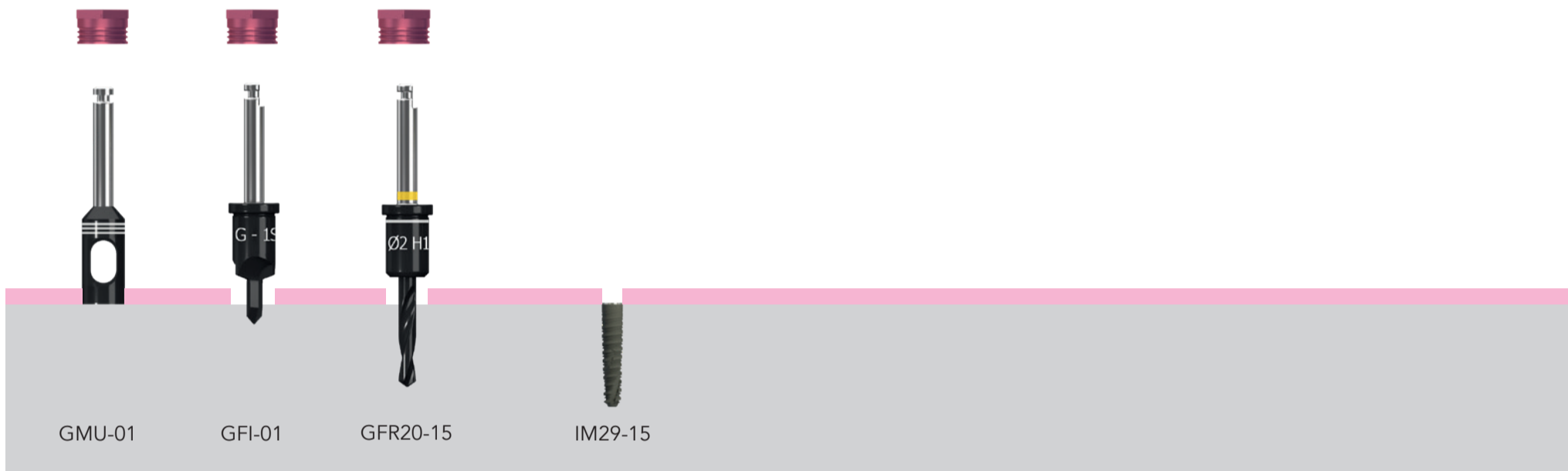


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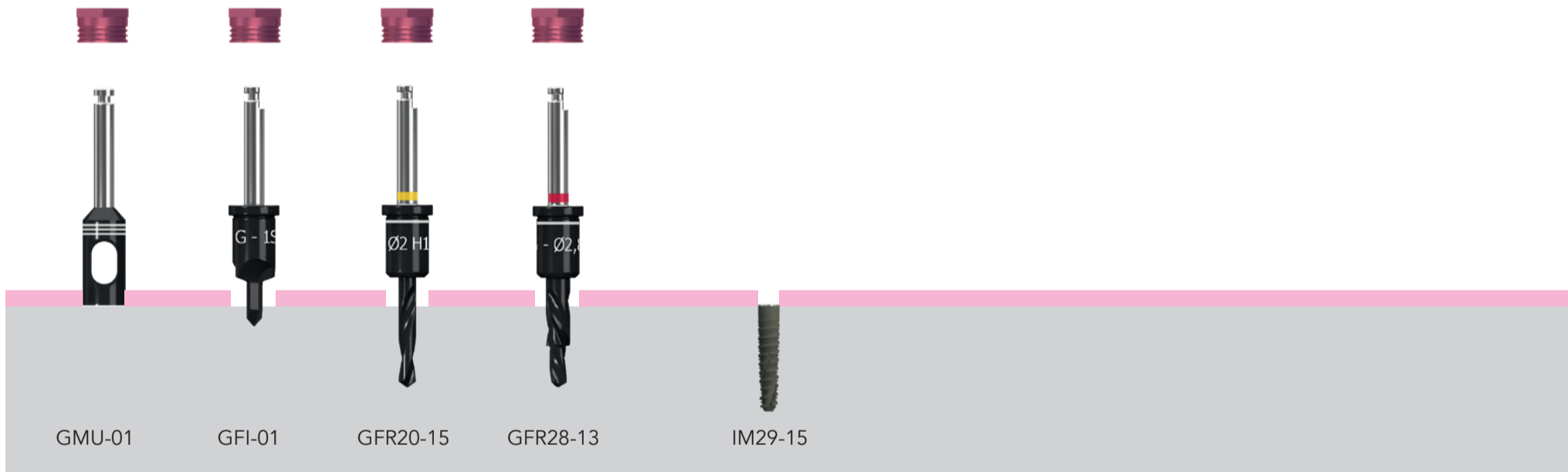
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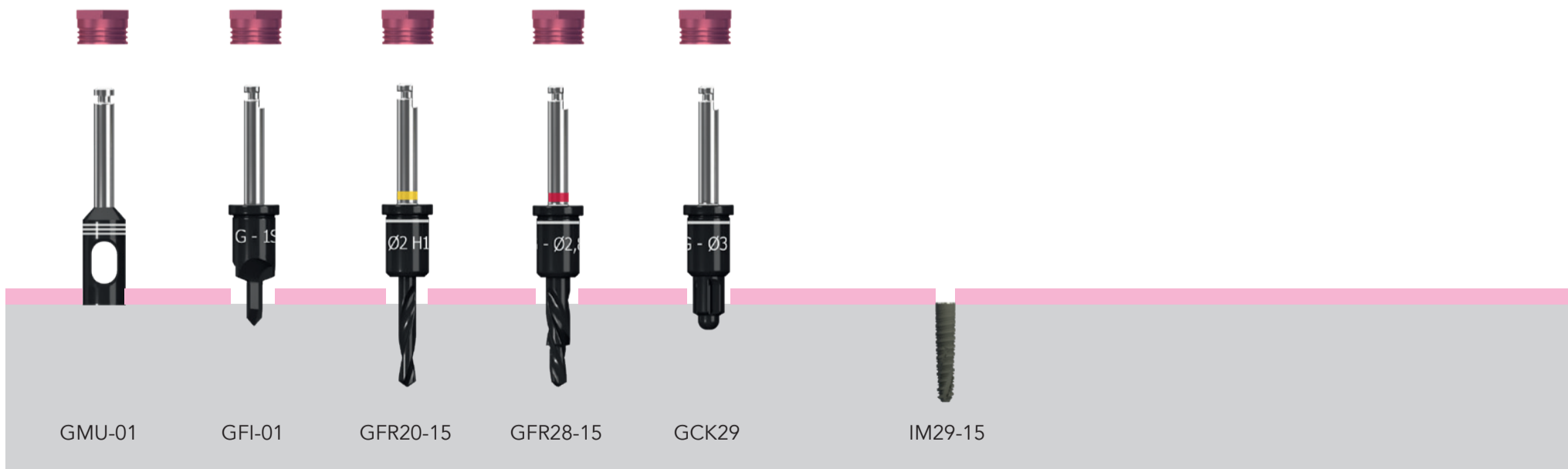
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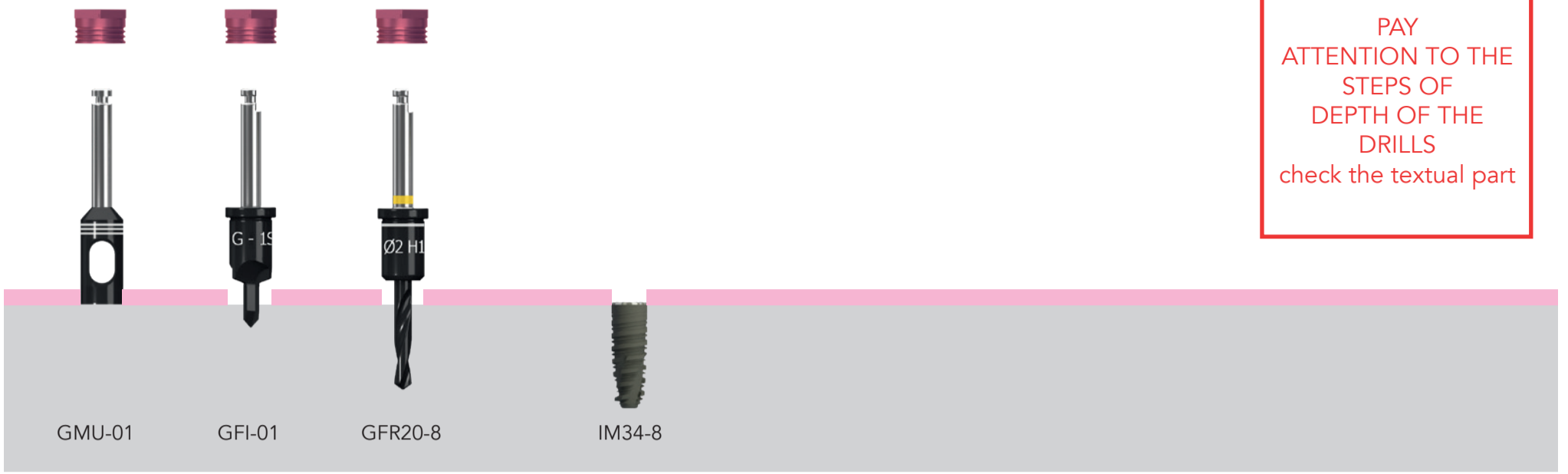


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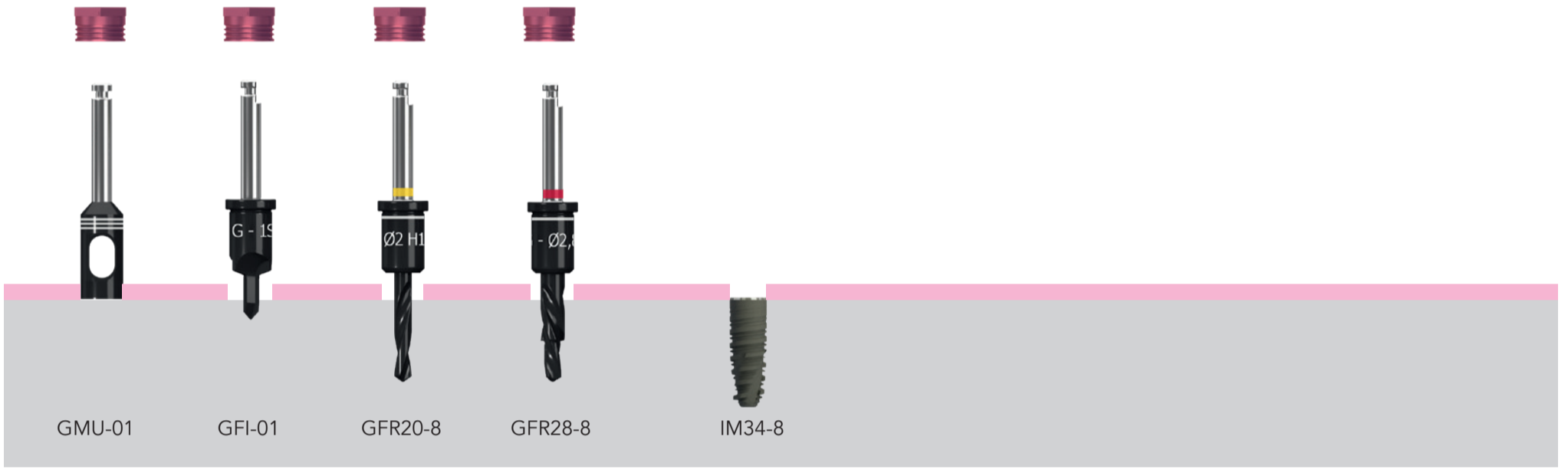


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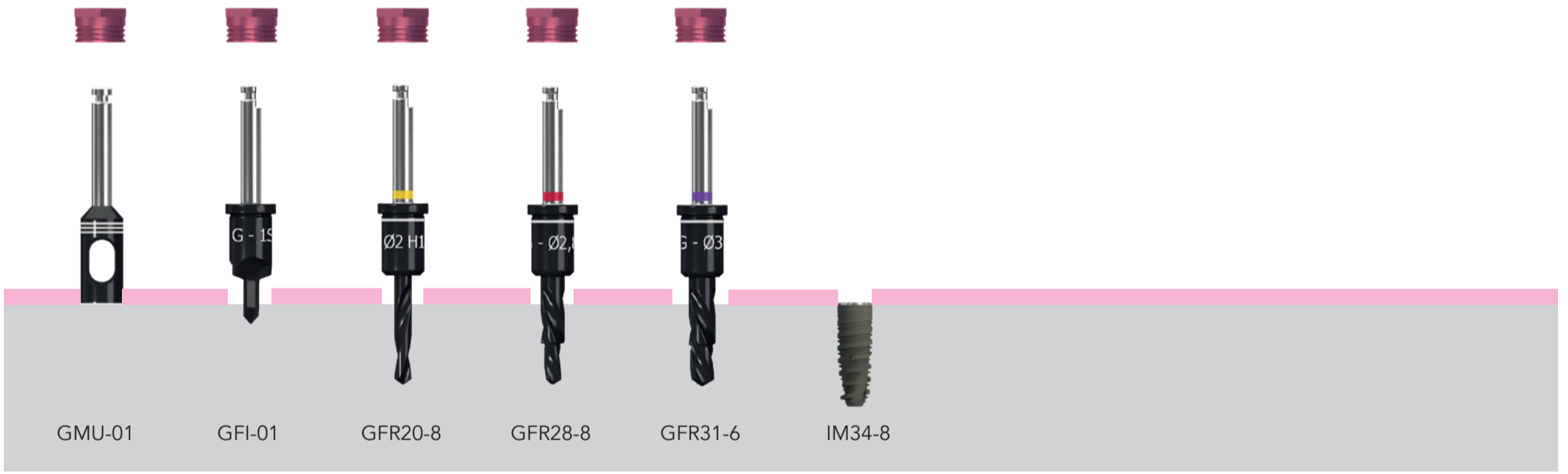
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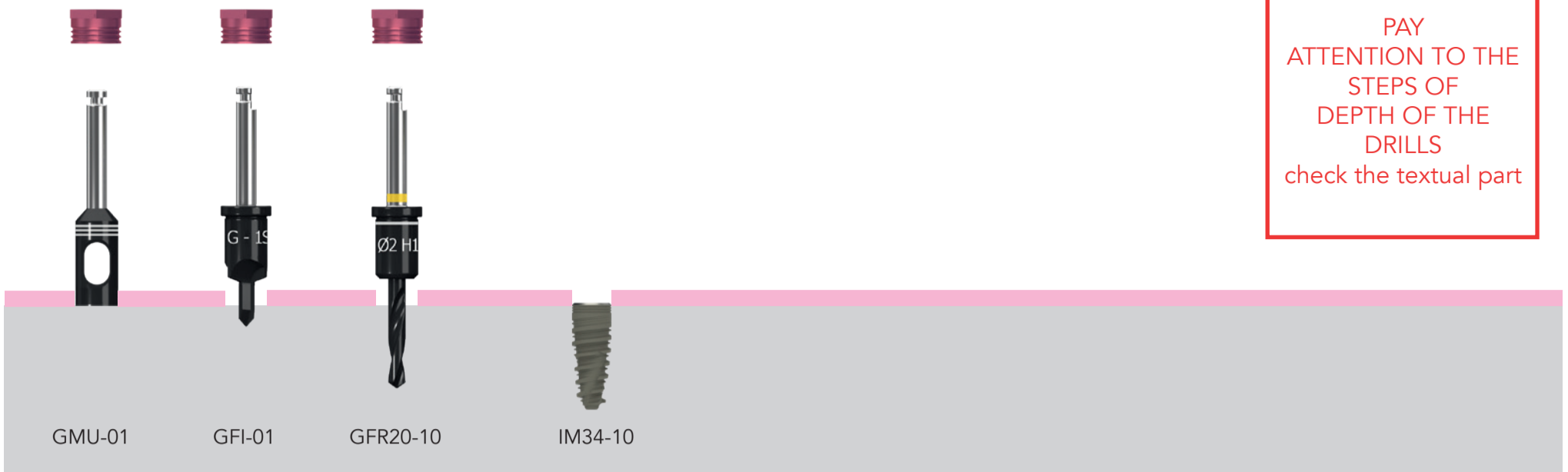


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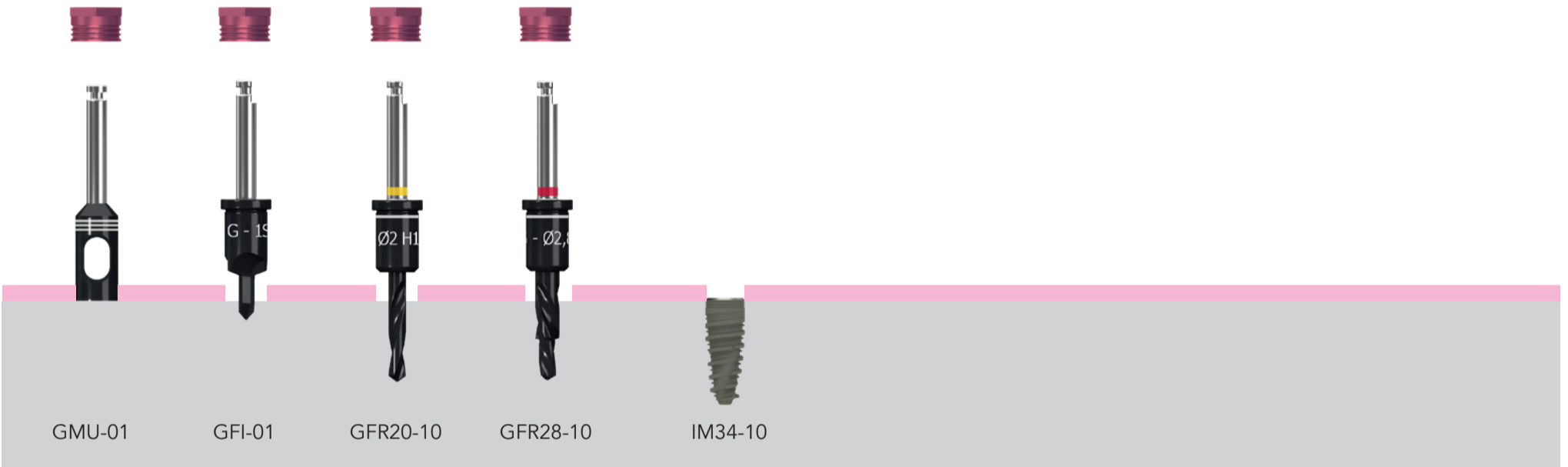


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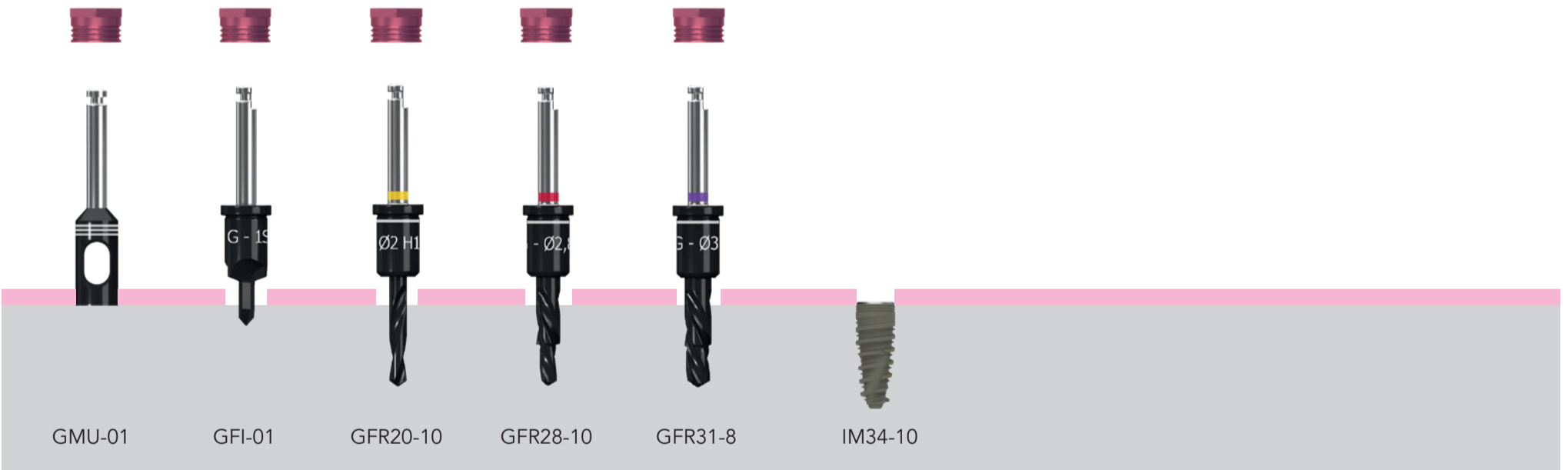
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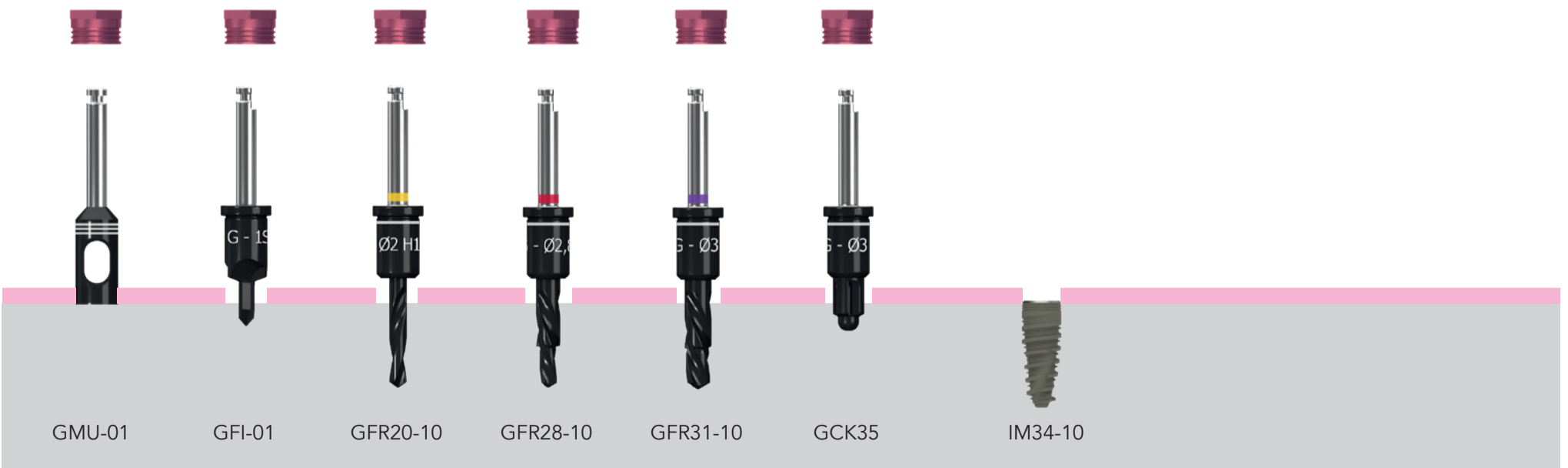
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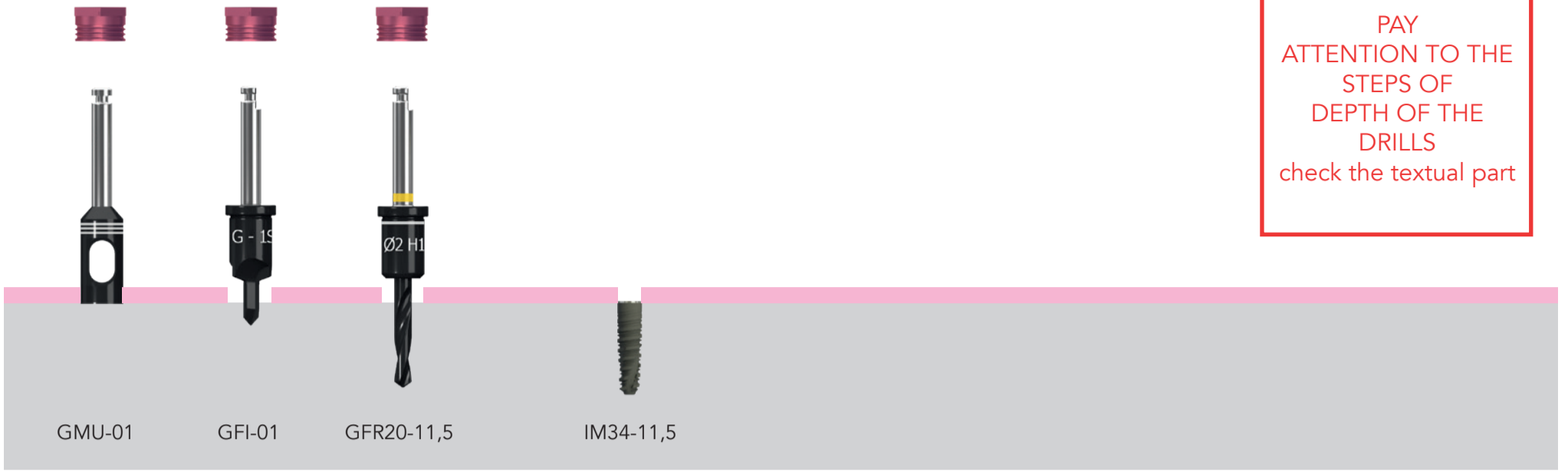


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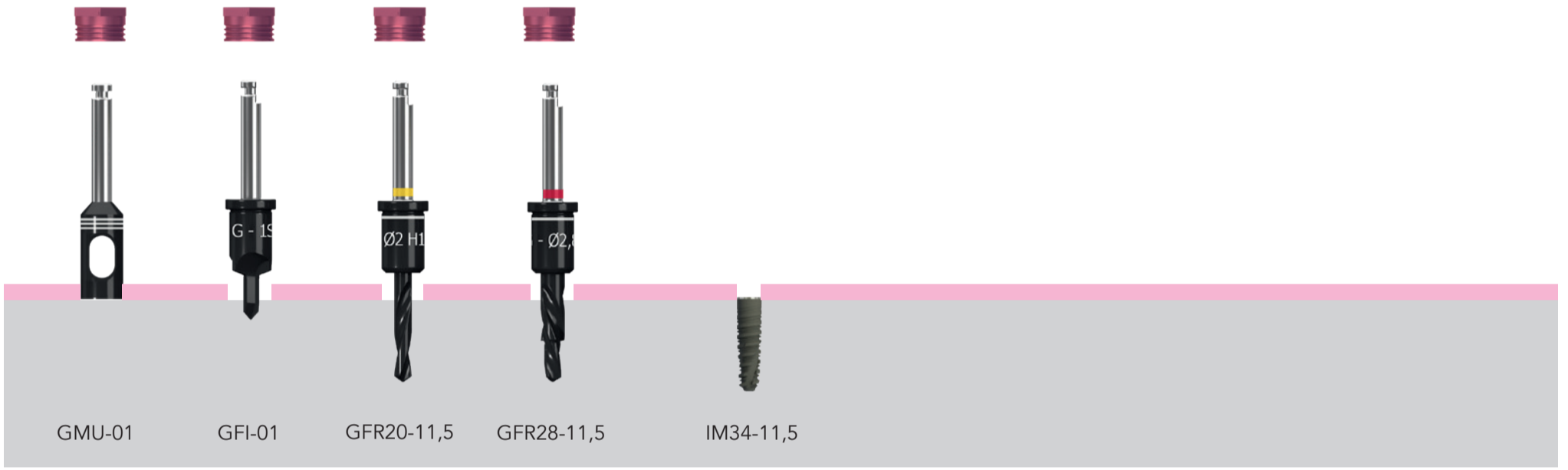


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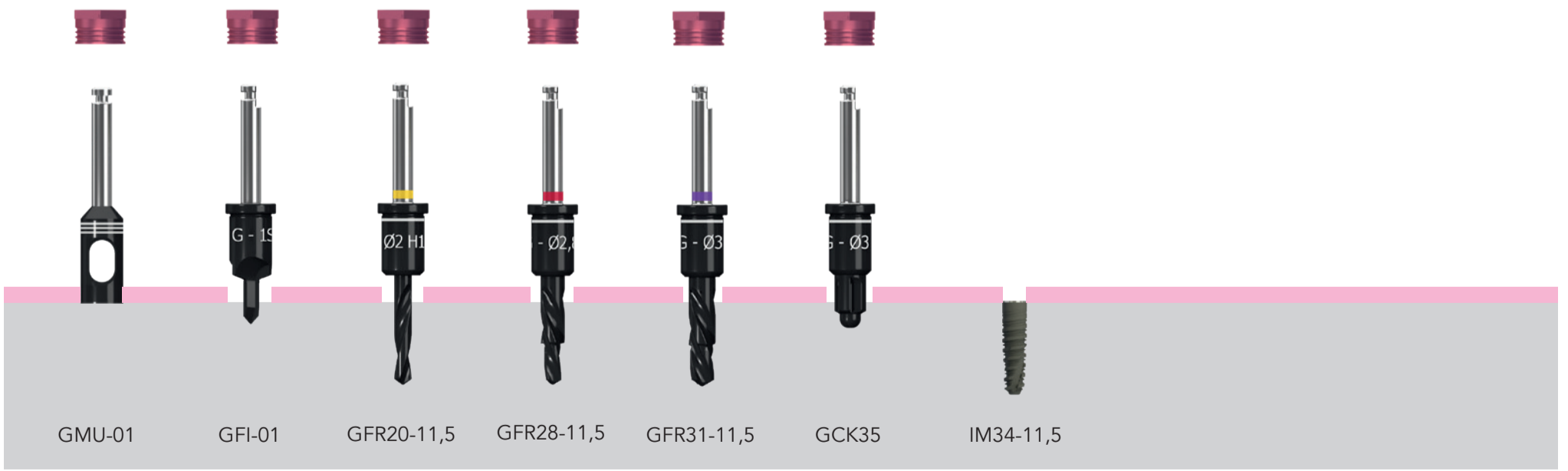
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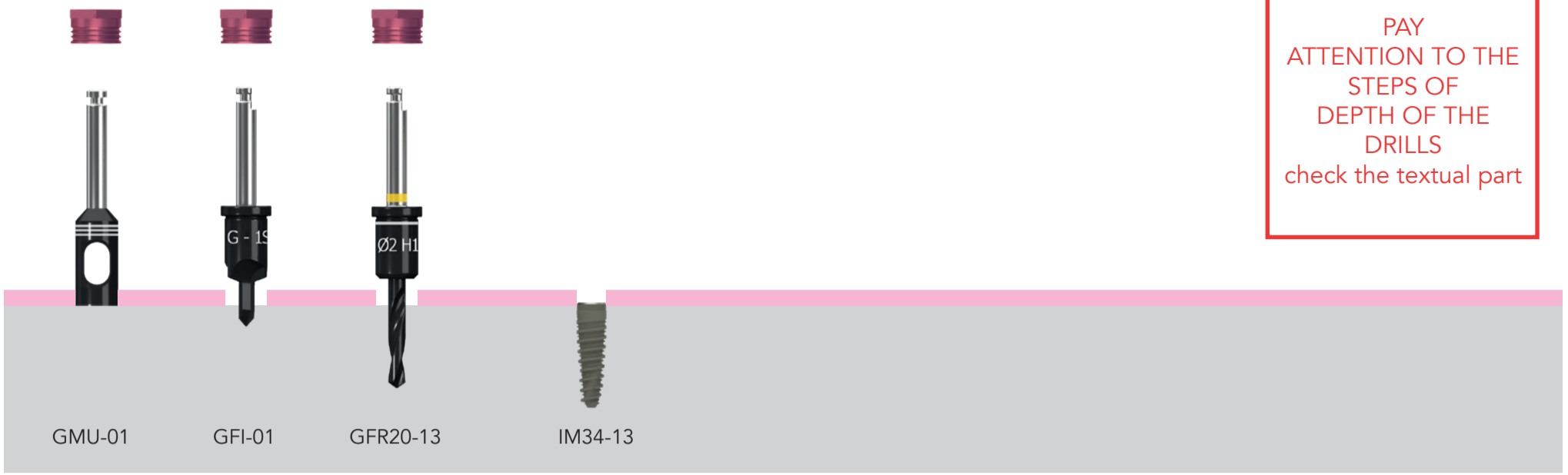


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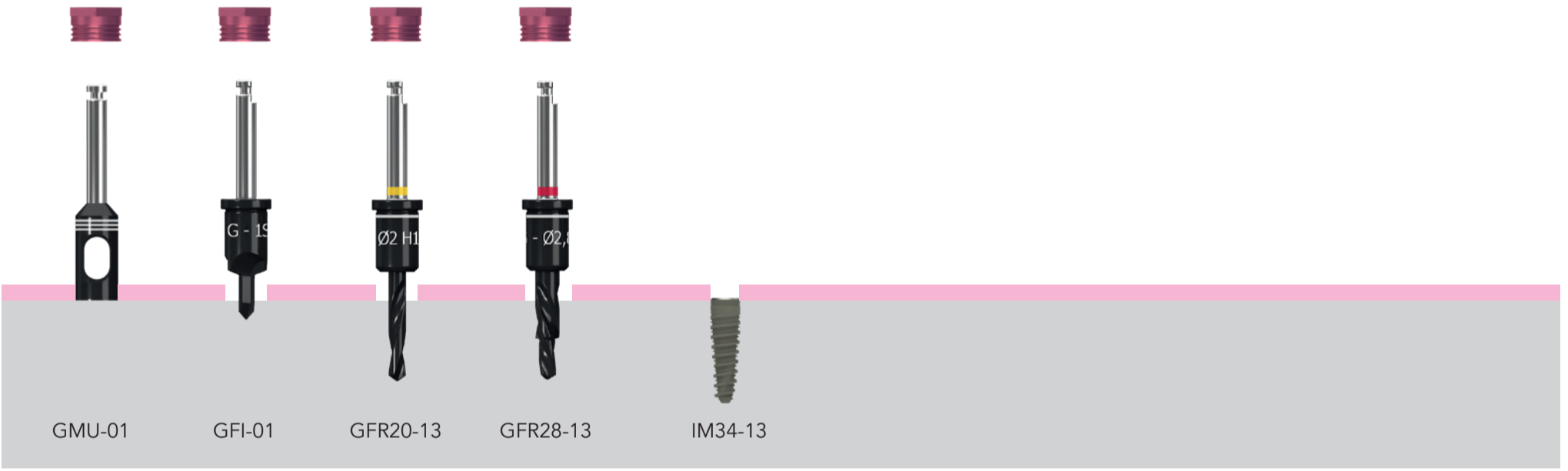


PAY ATTENTION TO THE STEPS OF DEPTH OF THE DRILLS check the textual part

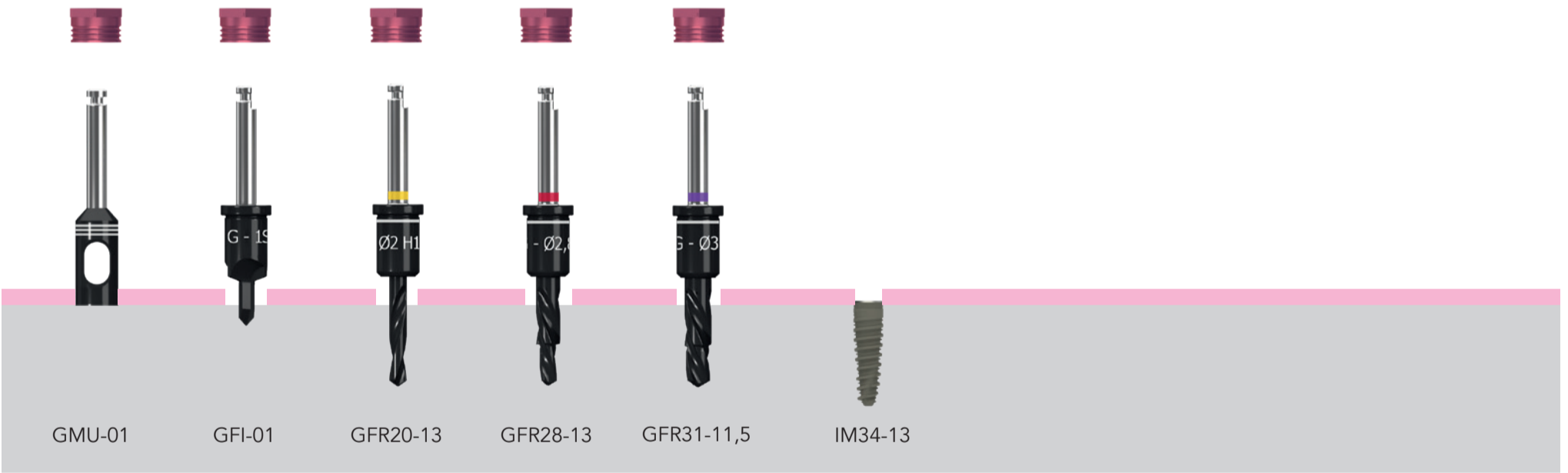
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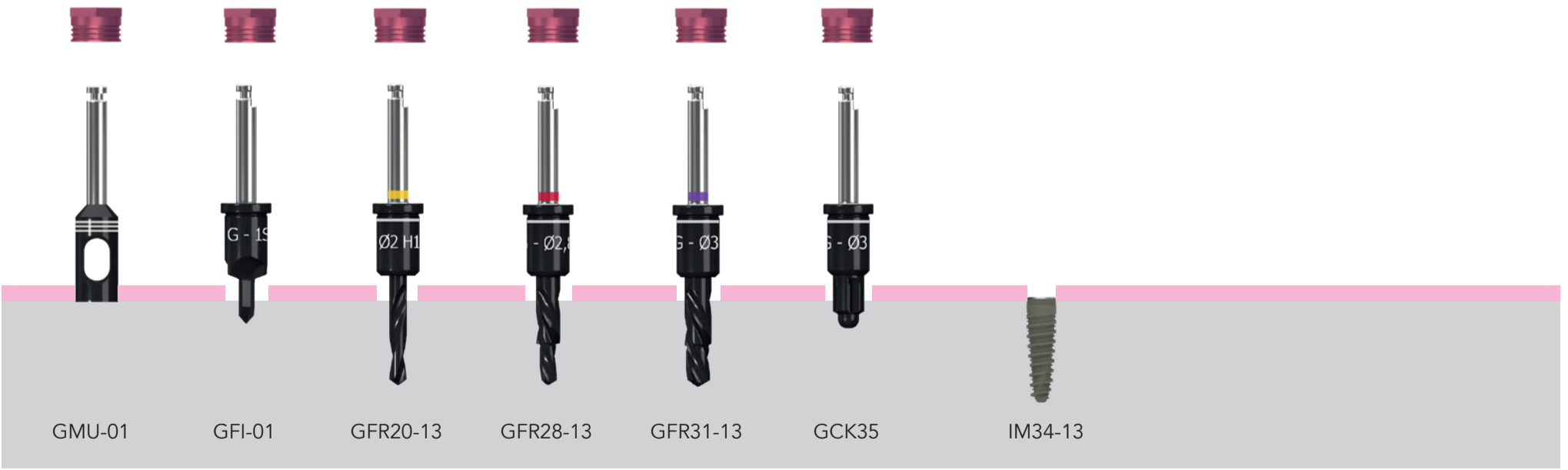
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D2

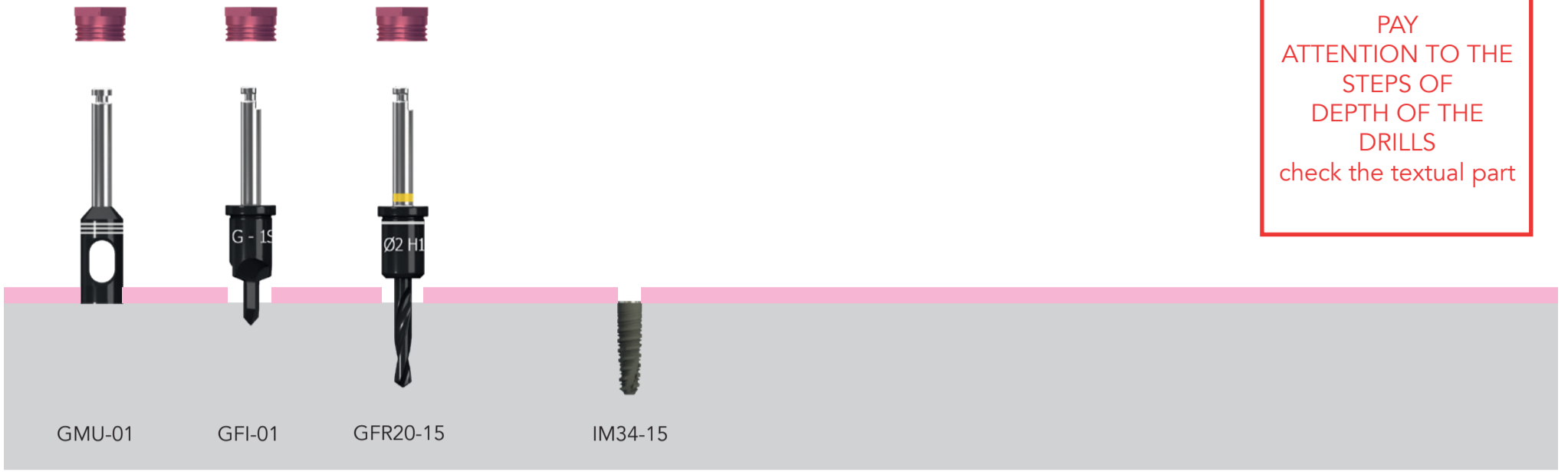


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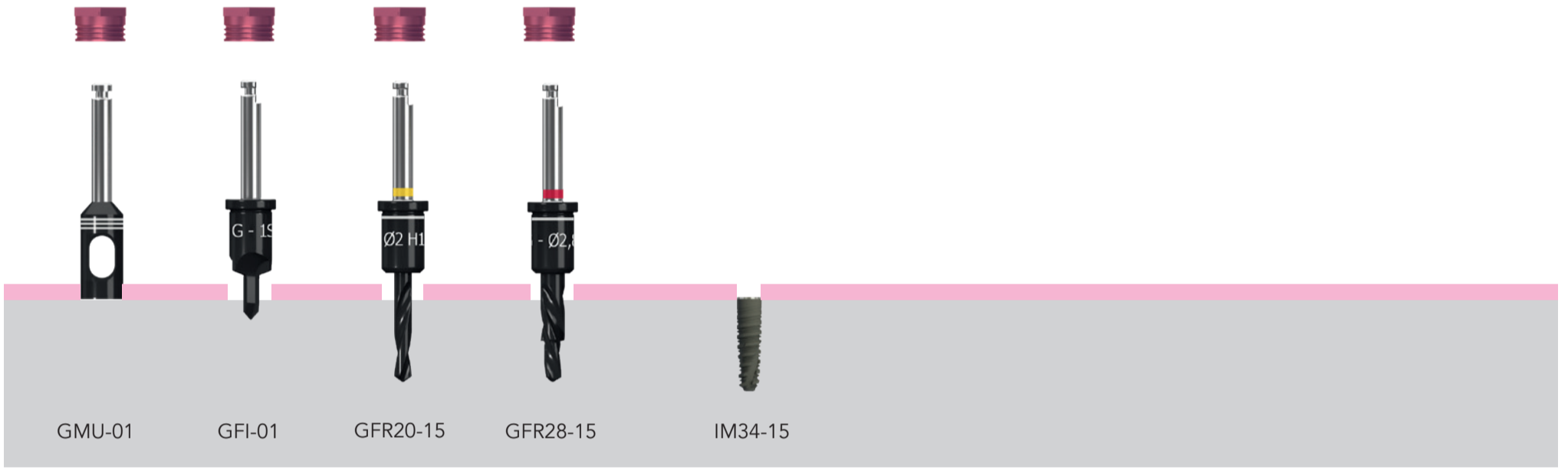


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DRILLS
check the textual part

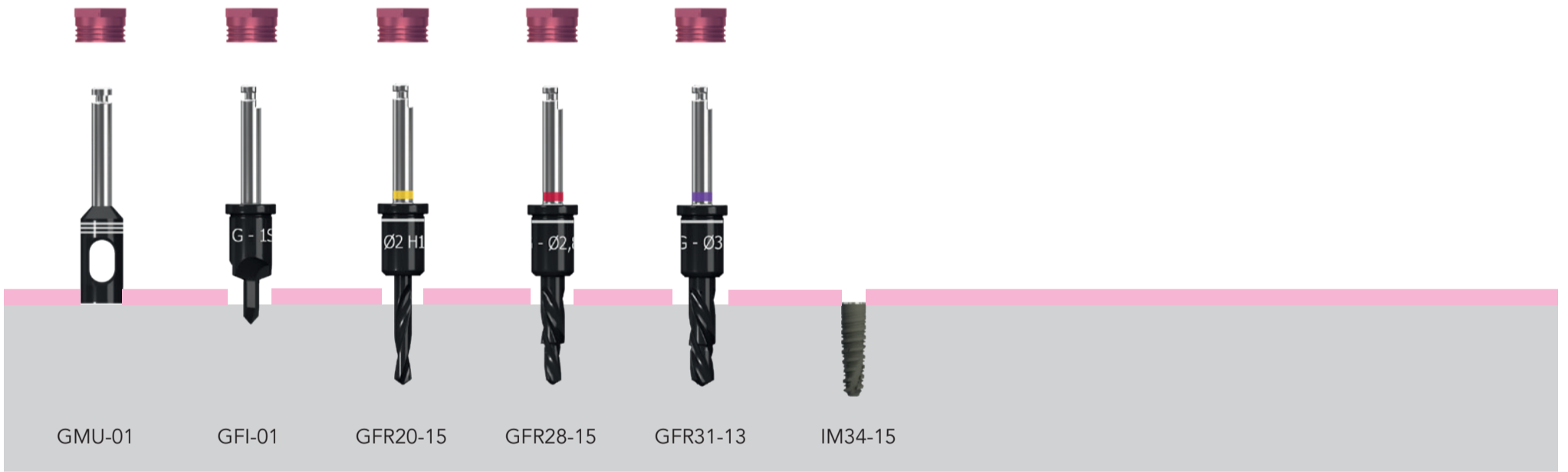
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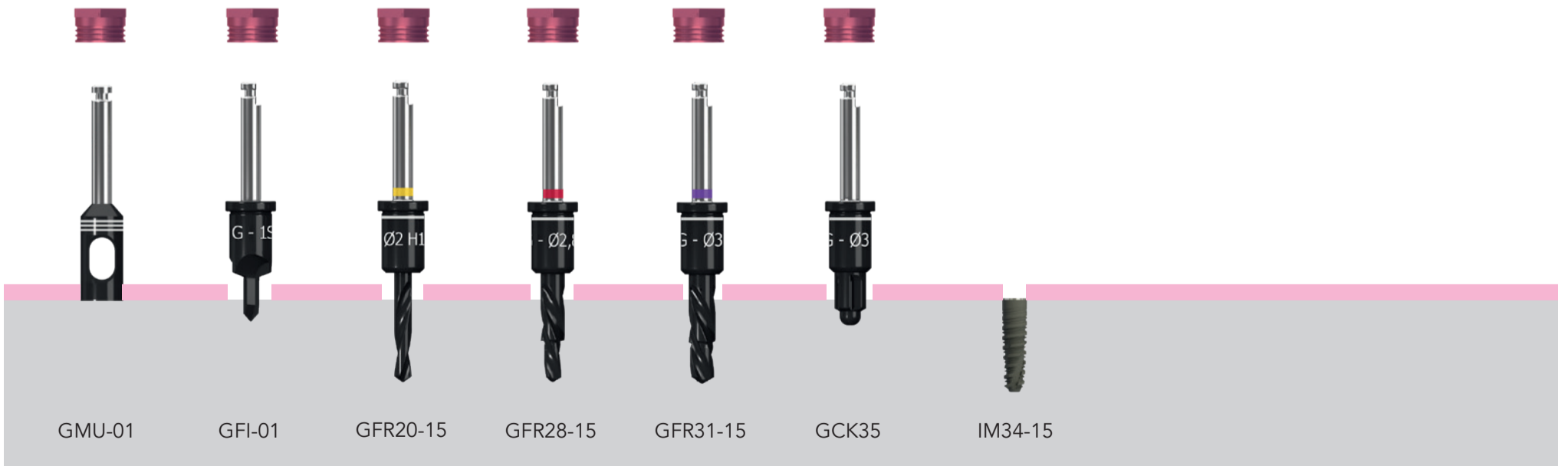
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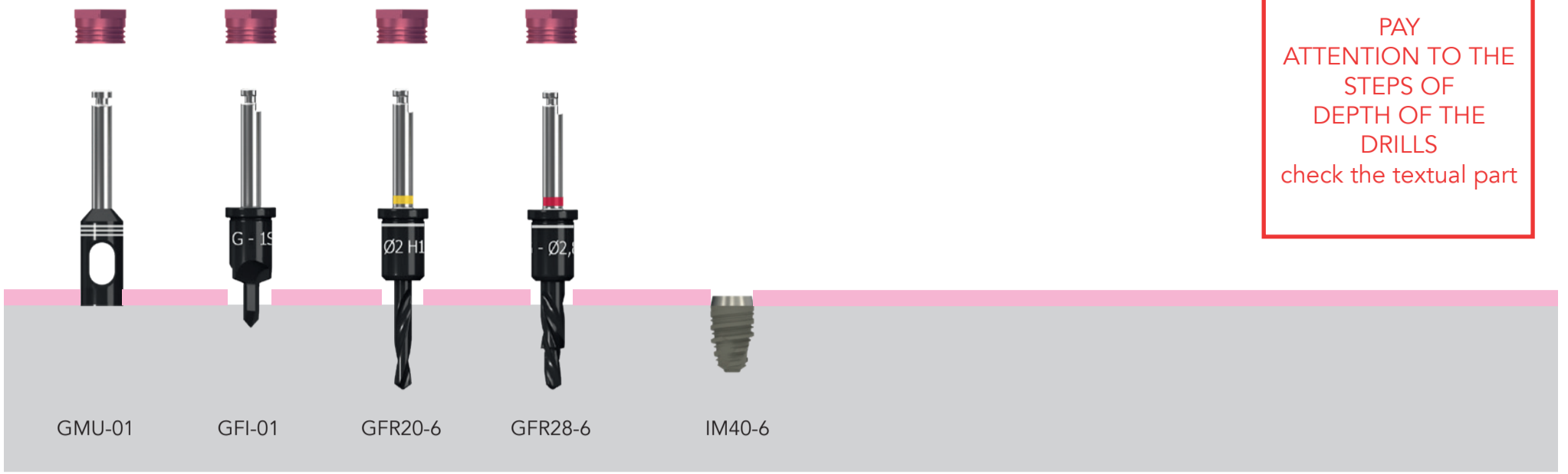


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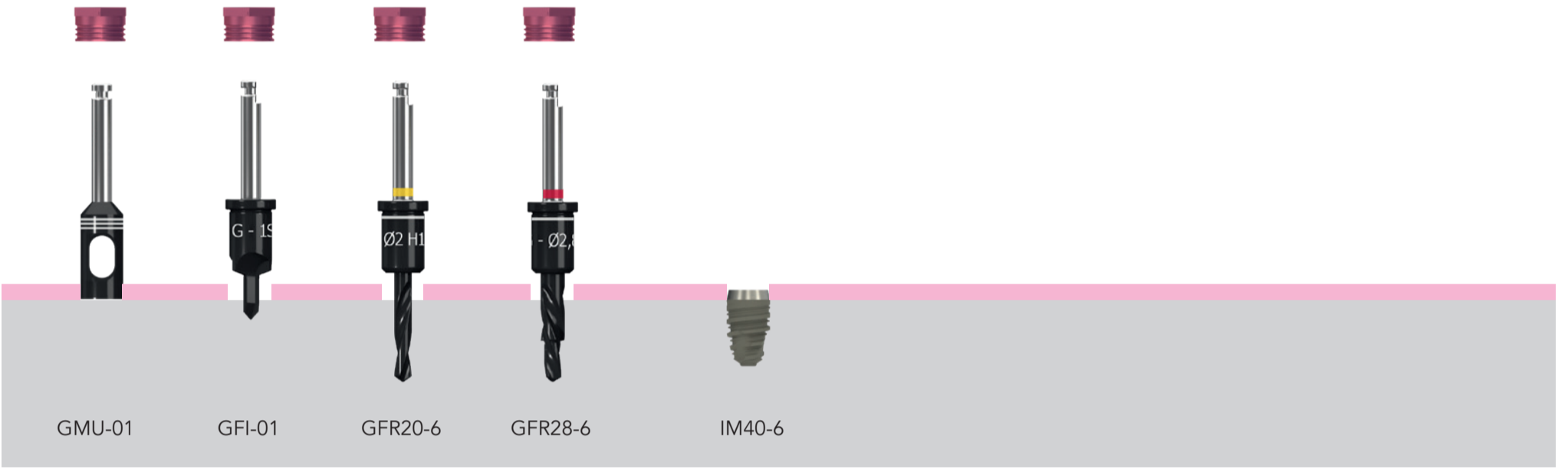


PAY ATTENTION TO THE STEPS OF DEPTH OF THE DRILLS check the textual part

D4



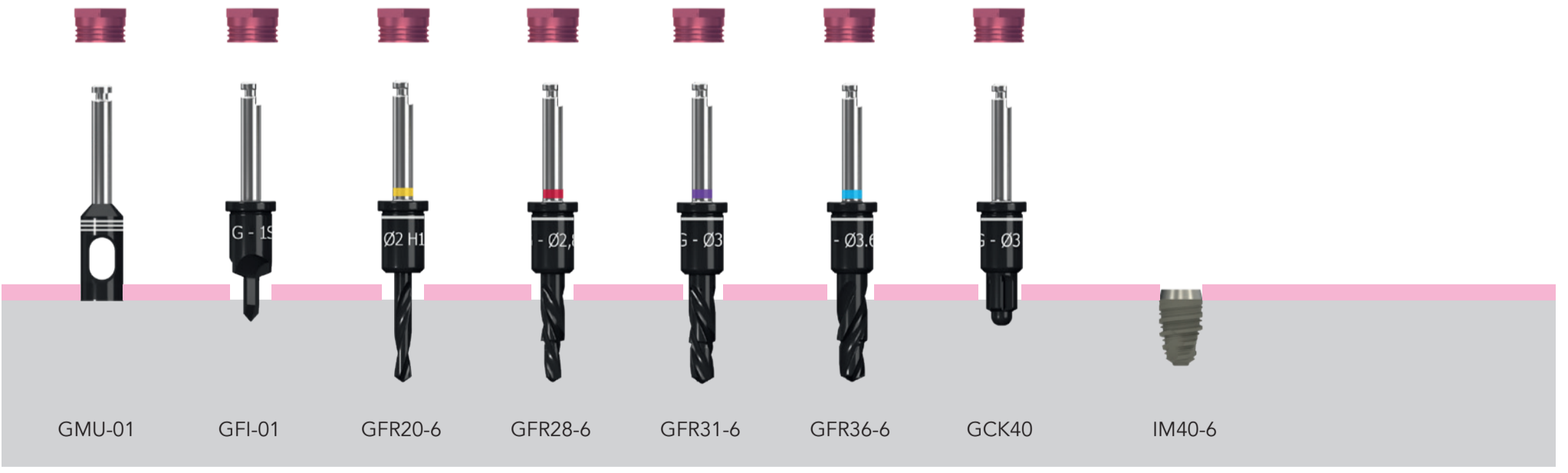
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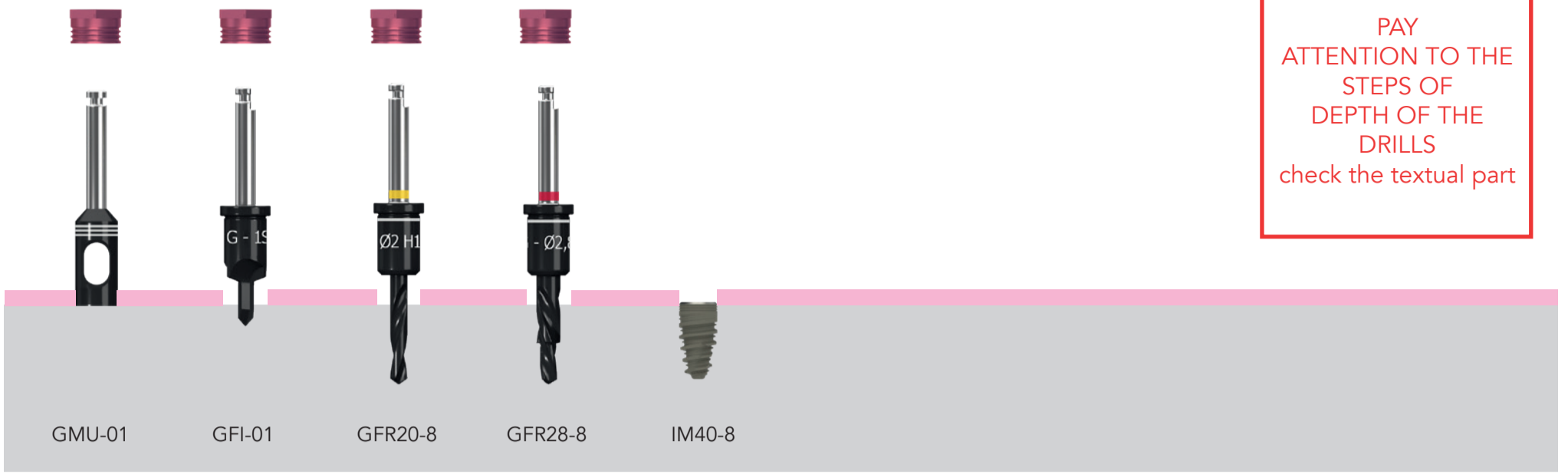


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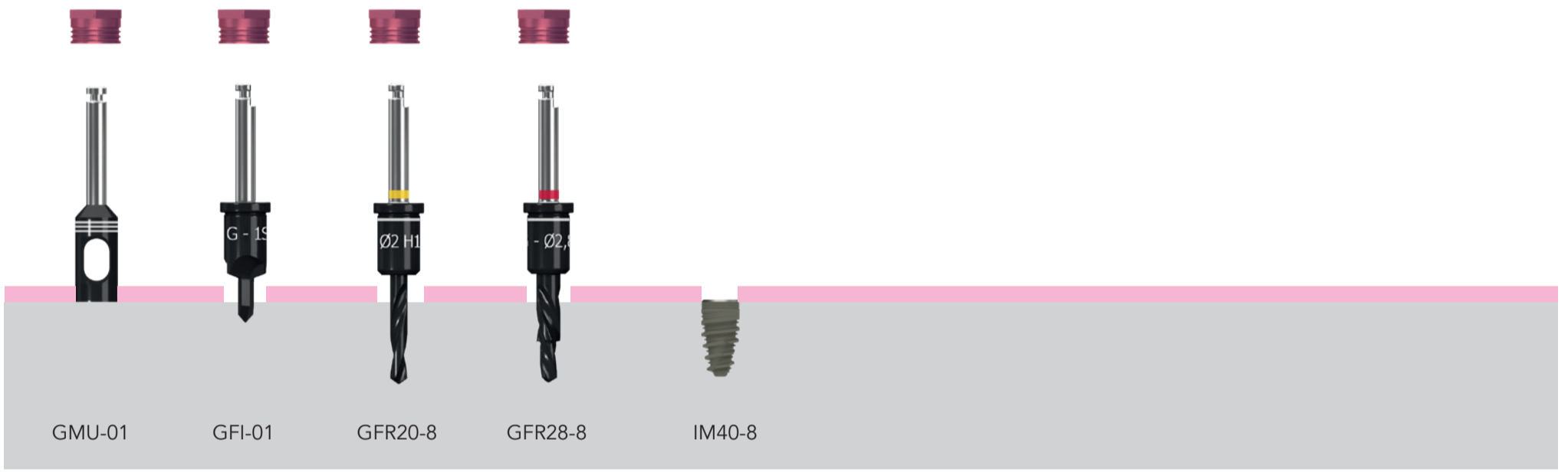


PAY ATTENTION TO THE STEPS OF DEPTH OF THE DRILLS check the textual part

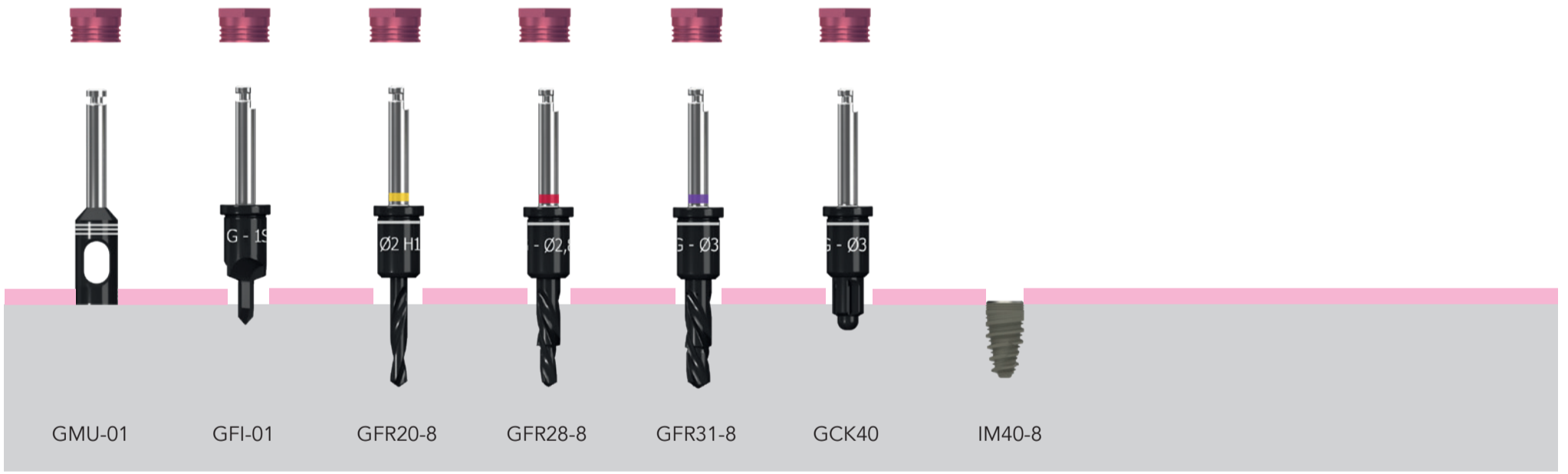
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D3



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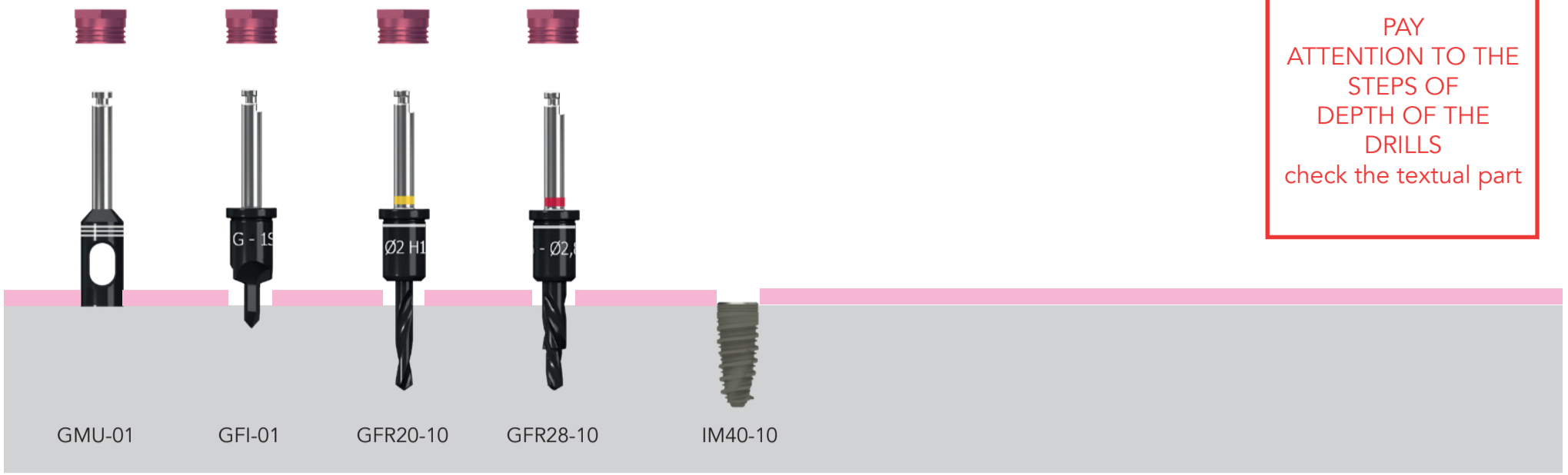


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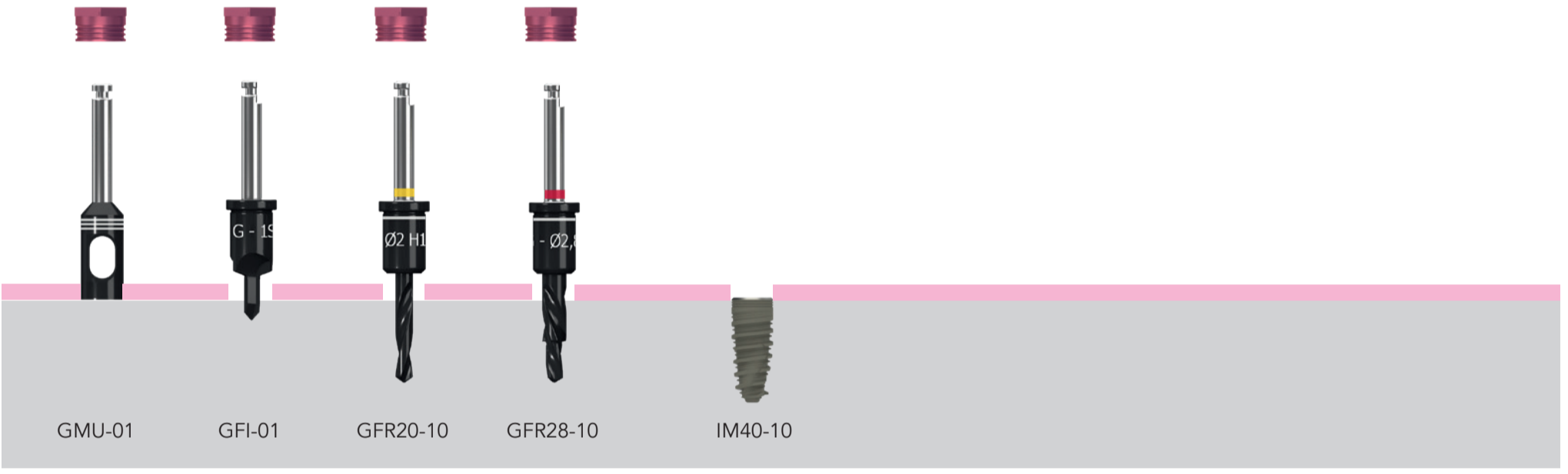


PAY ATTENTION TO THE STEPS OF DEPTH OF THE DRILLS check the textual part

D4



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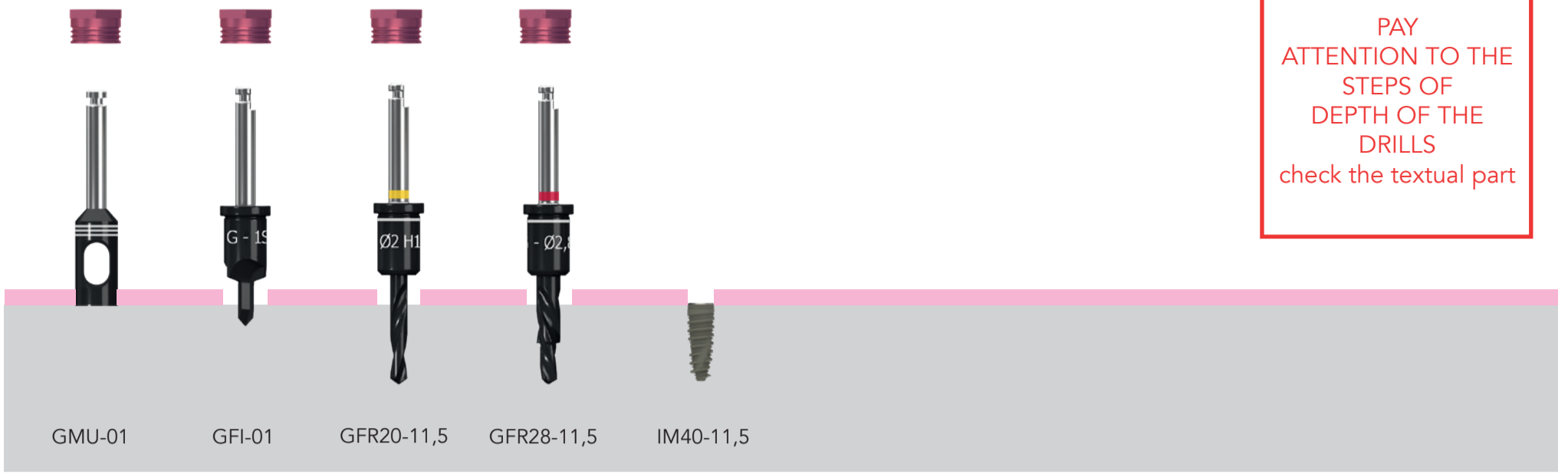


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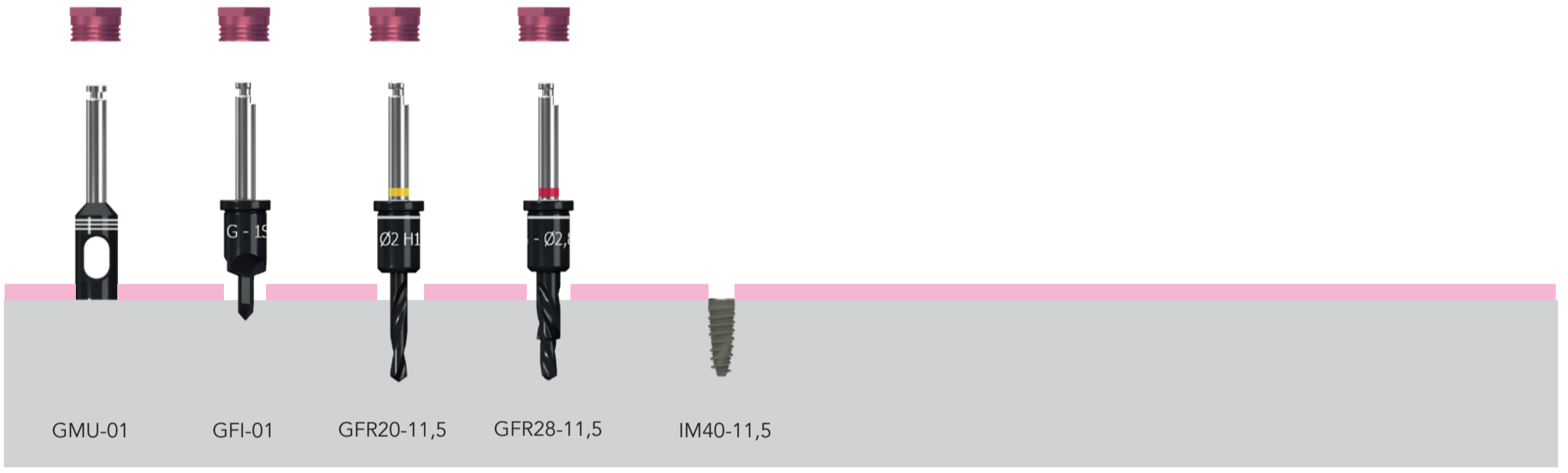


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check the textual part

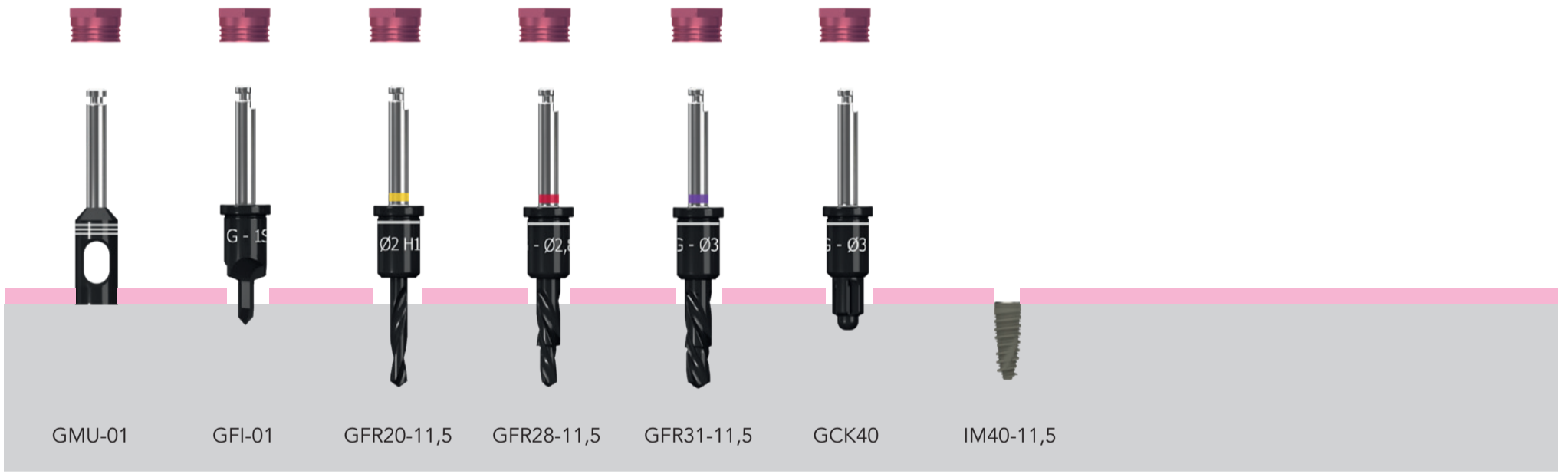
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D3



D2

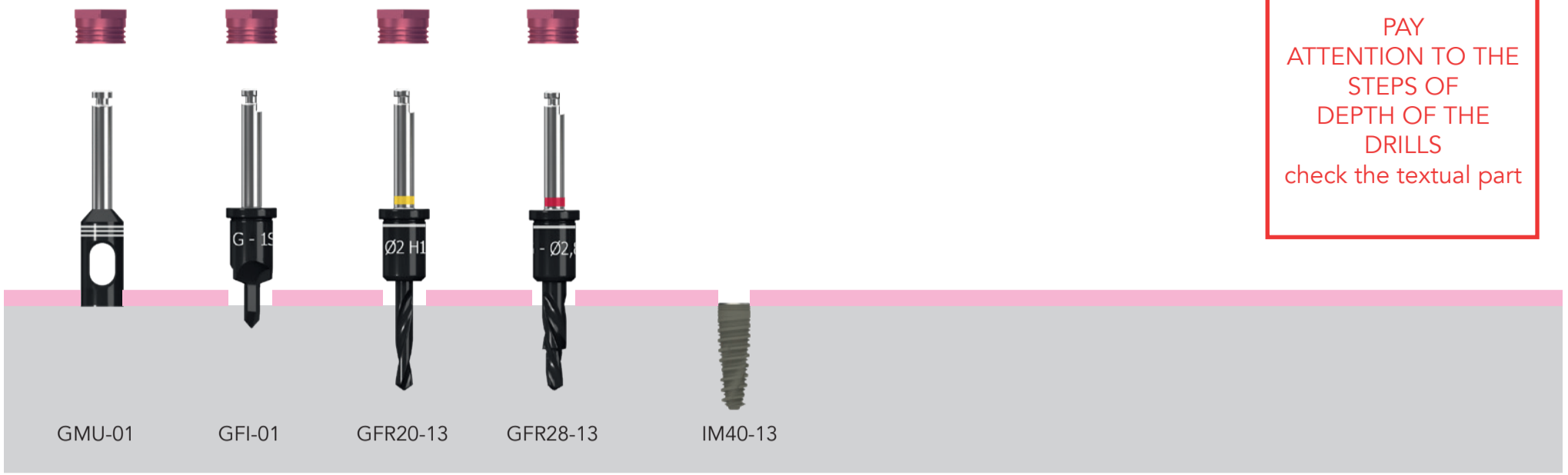


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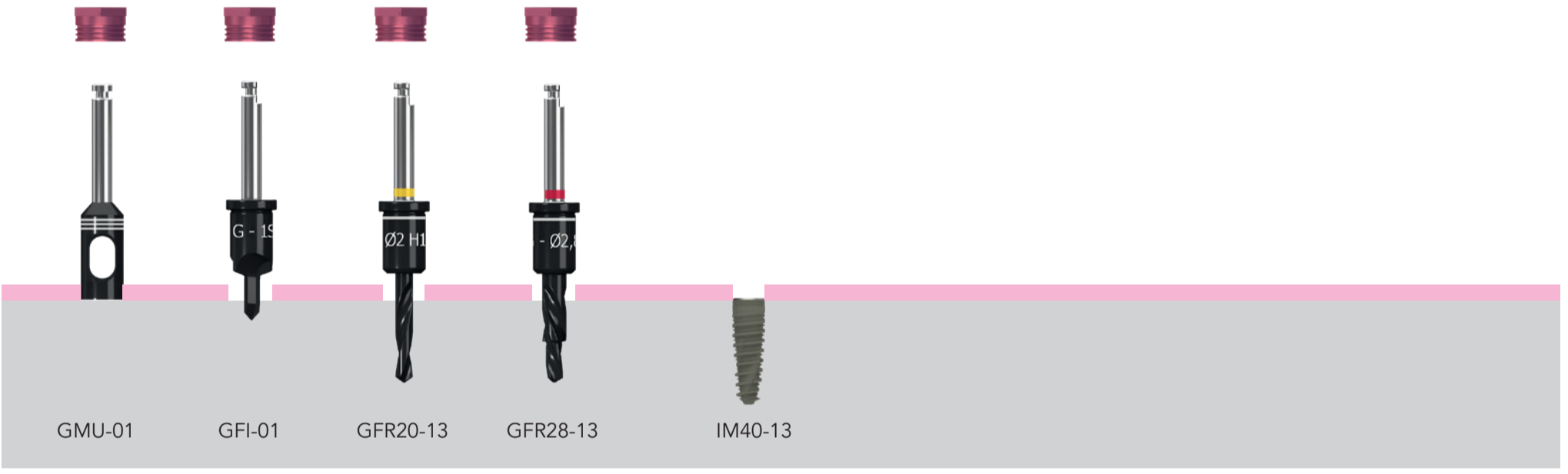


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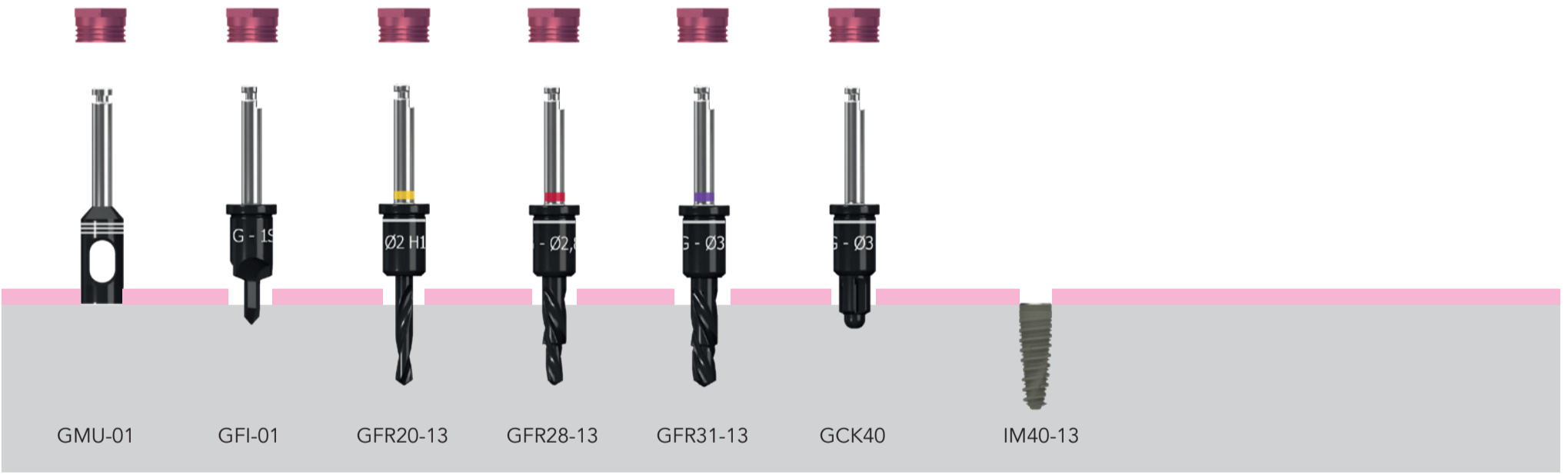
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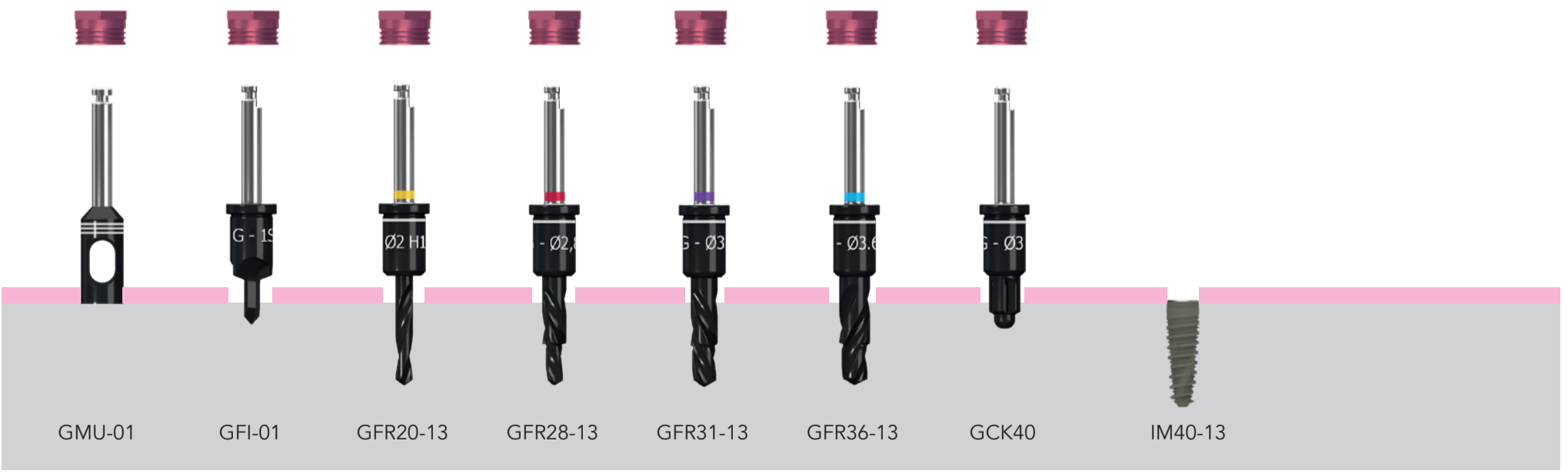
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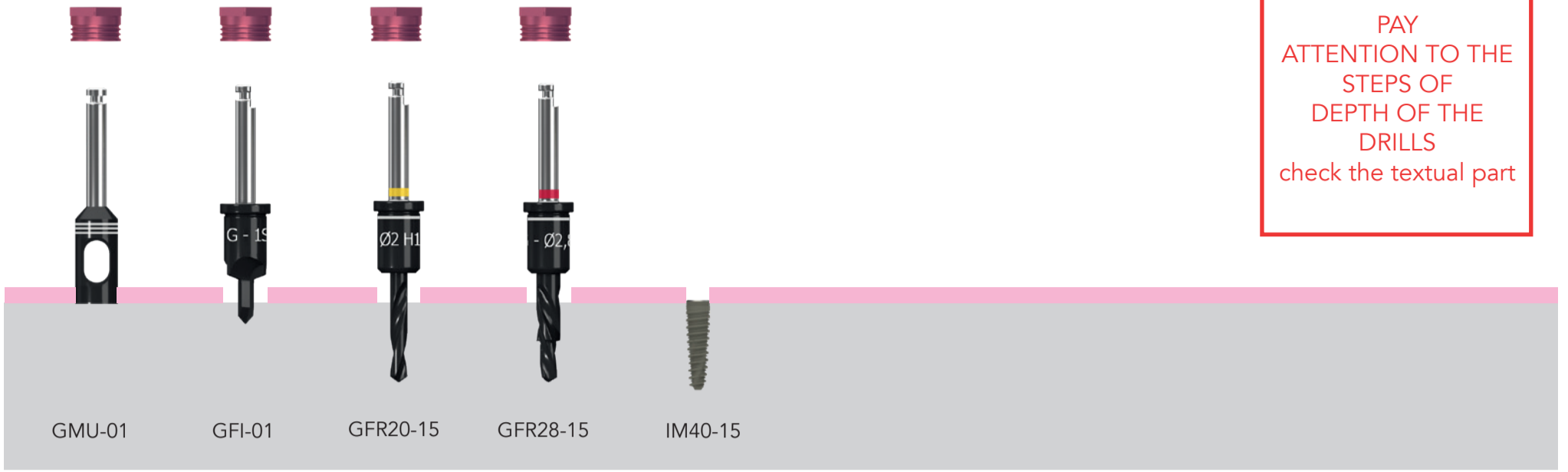


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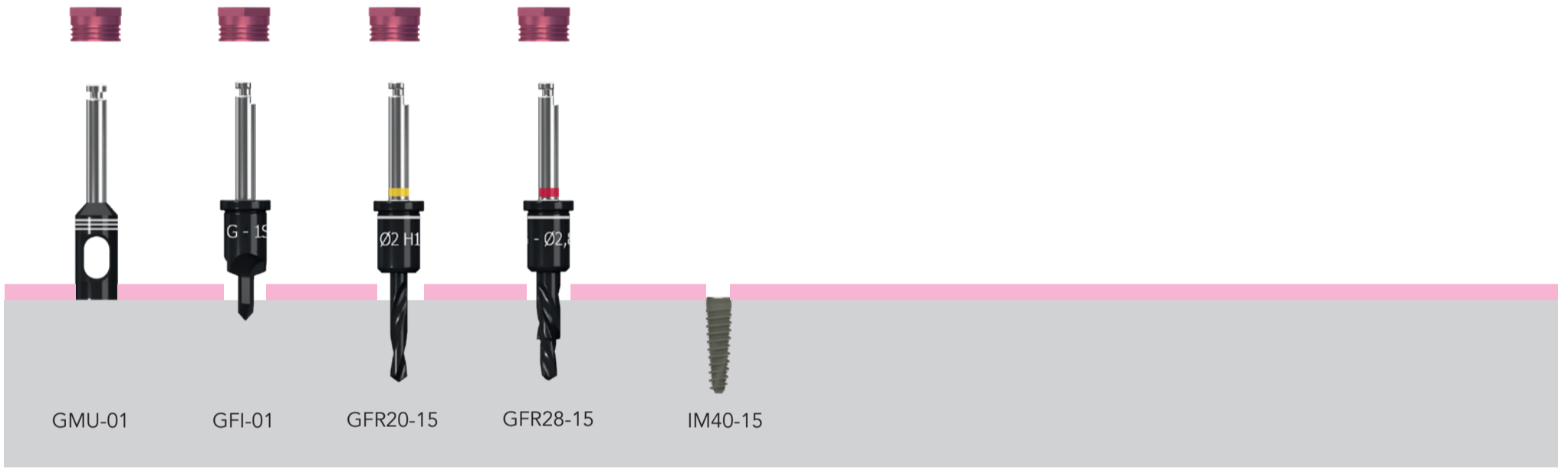


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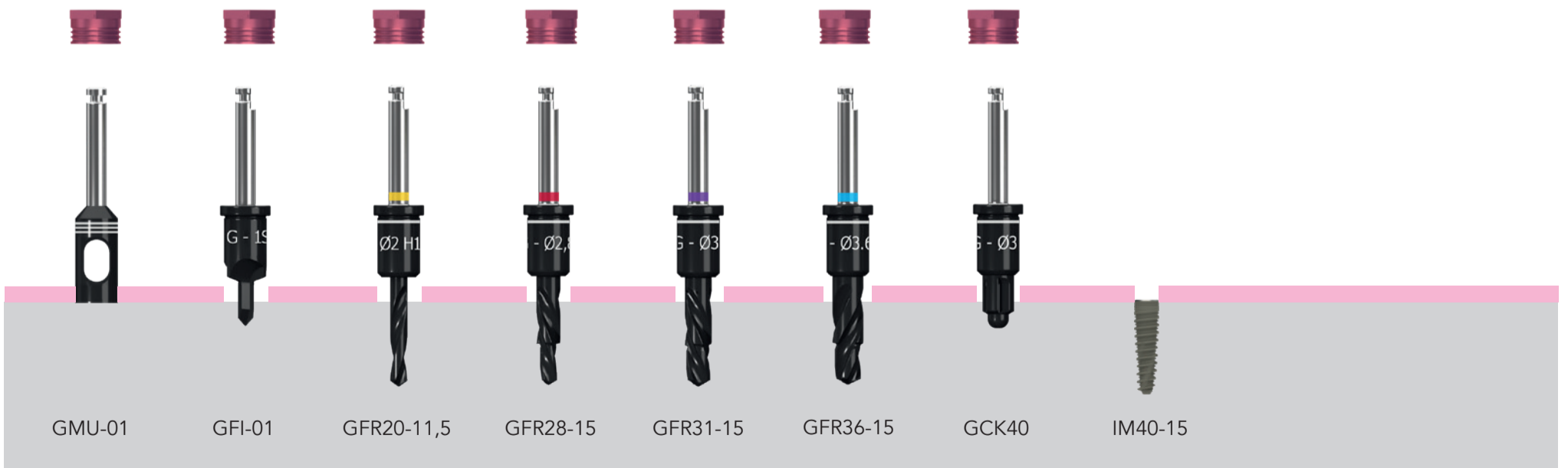
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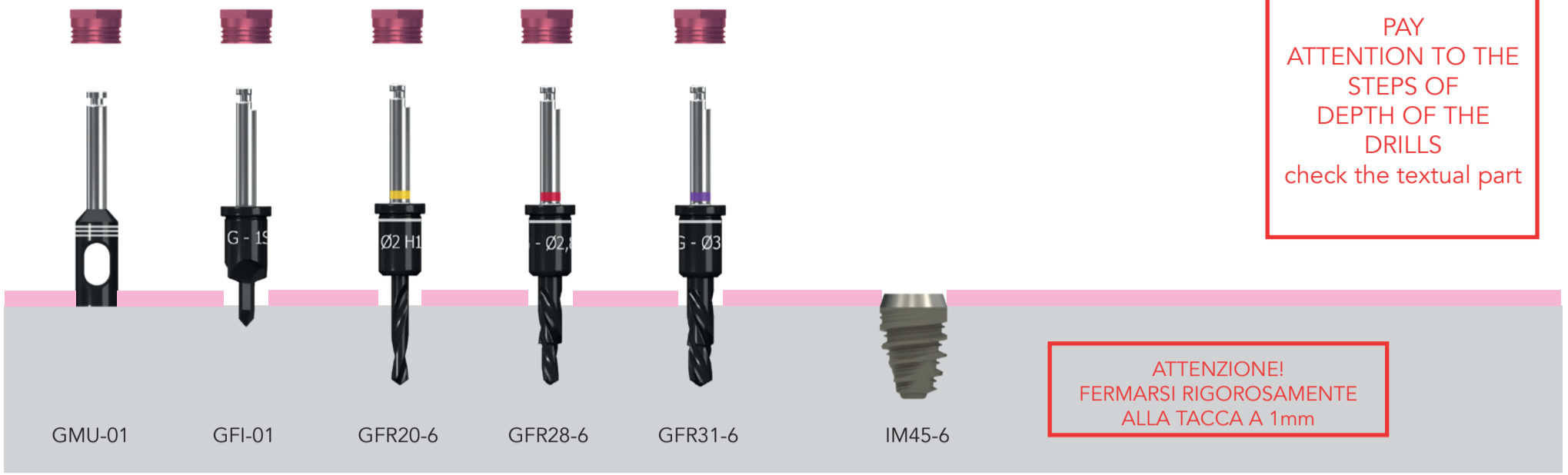


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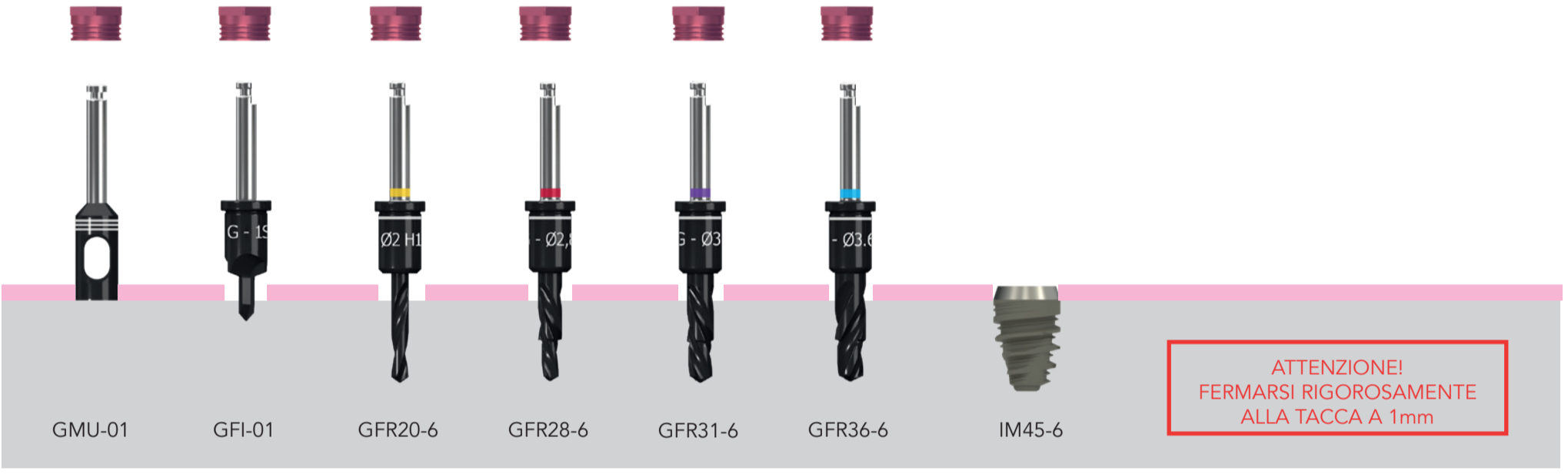


PAY ATTENTION TO THE STEPS OF DEPTH OF THE DRILLS check the textual part

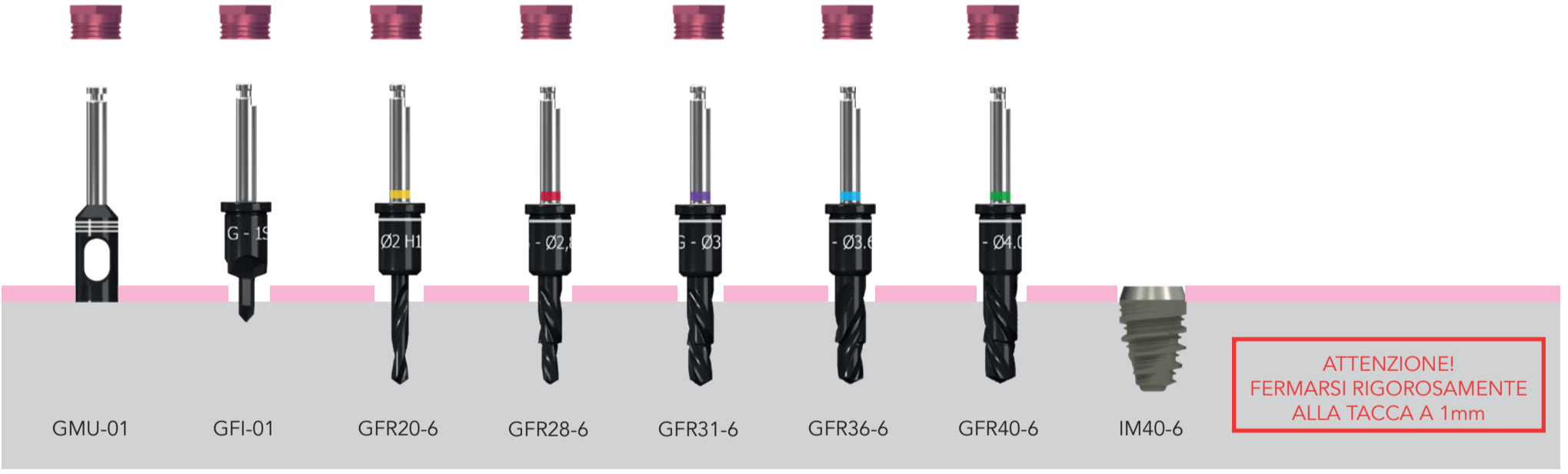
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D2



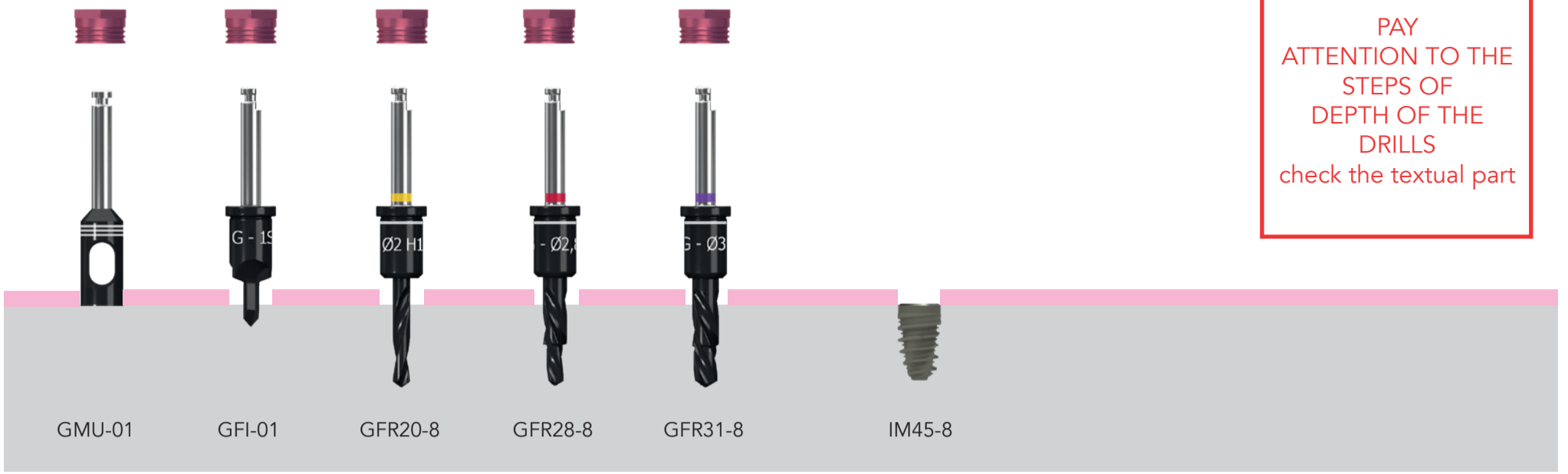
D1



ATTENZIONE! FERMARSI RIGOROSAMENTE ALLA TACCA A 1mm

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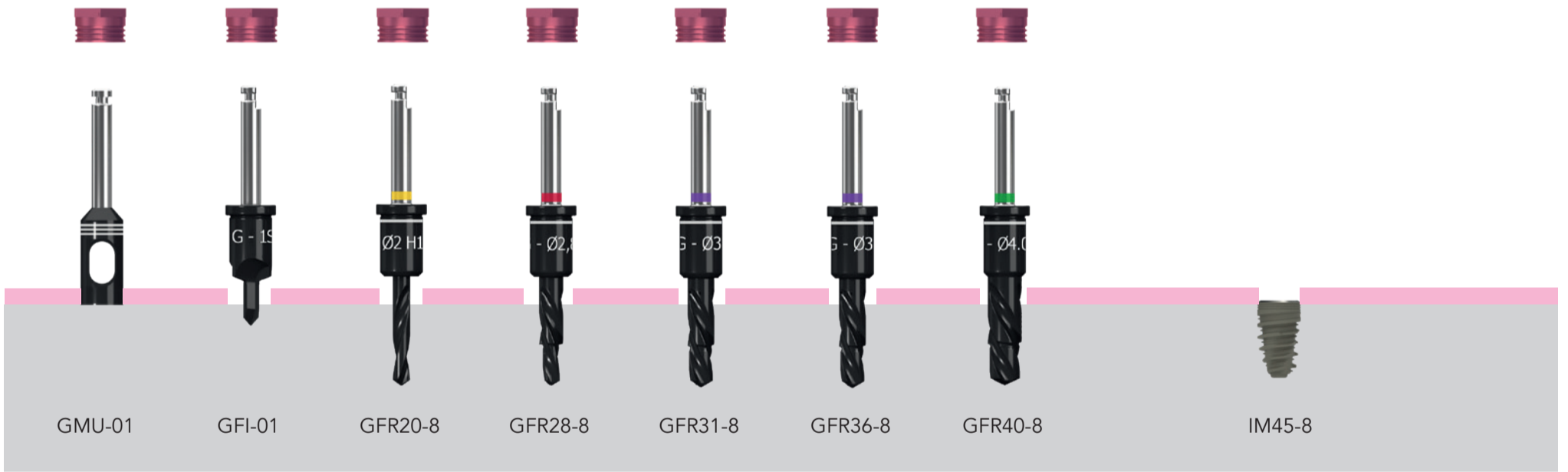
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D3



D2

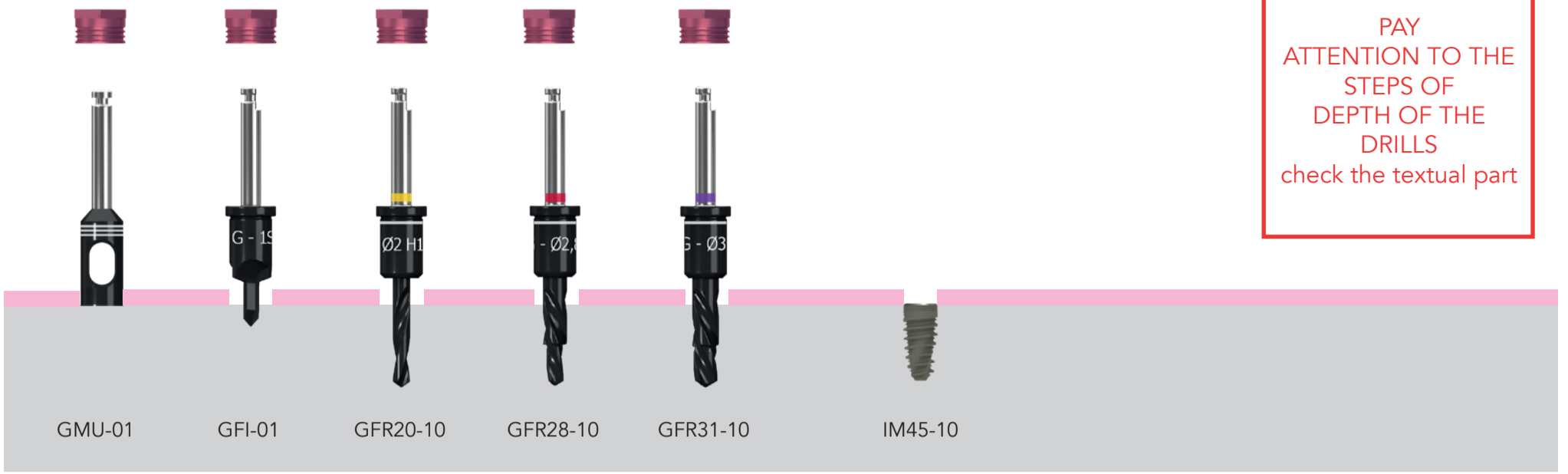


D1



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DEPTH OF THE
DRILLS
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D3



D2



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PAY ATTENTION TO THE STEPS OF DEPTH OF THE DRILLS check the textual part

D4



D3



D2

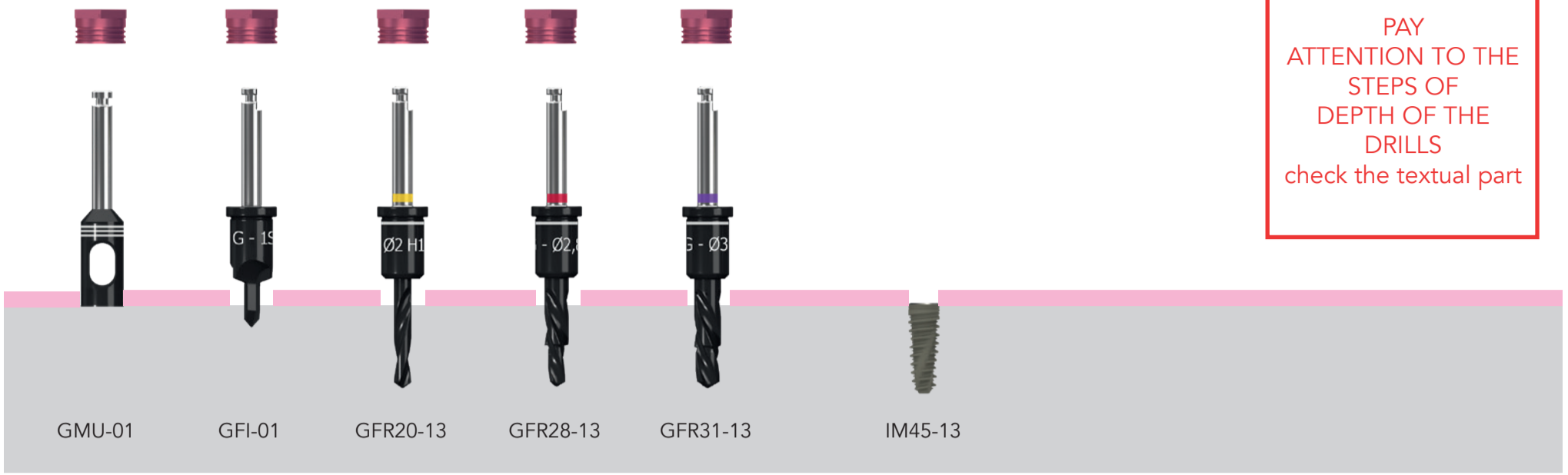


D1



PAY ATTENTION TO THE STEPS OF DEPTH OF THE DRILLS check the textual part

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D3



D2



D1



PAY ATTENTION TO THE STEPS OF DEPTH OF THE DRILLS check the textual part

D4



D3



D2



D1

