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CHAPTER 1

INTRODUCTION

Symbols Used

Symbol "Attention"

	This symbol stands for paying careful attention to the text embedded in this panel, because it contains important instructions regarding safety.

Although symbols facilitate the reading of the manual, a complete reading is recommended in order to avoid an unsafe or incorrect use of the device.

CE Marking, compliance with regulations and directives

This product is CE marked according to the European guidelines, in particular:

1. Directive 93/42/CEE on medical devices (adopted in Legislative Decree 46/97).
2. Directive 2002/95/CE RoHS (adopted in Legislative Decree 151/2005).
3. Directive 2002/96/CE RAEE (adopted in Legislative Decree 151/2005).

Conformity was obtained by complying with the following regulations:

- CEI EN 60601-1:1998 Electromedical devices. Part 1: General Safety Standards.
- CEI EN 60601-1-2:2003-07 Electromedical devices. Part 1: General Safety Standards 2- Collateral Standard: Electromagnetic compatibility - Limitations and tests.
- CEI EN 60601-1-4:1997 Electromedical devices. Part 1: General Safety Standards 2- Collateral Standard: Programmable electromedical systems.
- UNI CEI EN ISO 14971:2007 Medical devices. Application of risk management to medical devices.
- UNI EN ISO 9001:2008 Quality management systems.
- UNI EN ISO 13485:2004 Quality management systems. Medical Devices.

Product Identification

This handbook has been written referring to the following device:

- Implant-Weld 300 - Intraoral welder for dental use

Accessories supplied

Item	
HANDPIECE - SURGICAL TONGS	PAMANPIN001.1
COPPER ELECTRODES	CEELTEWD6090AAA
CONTROL PEDAL	PAINTPED003.1
CONNECTING CABLES FOR TONGS	PACAVEWD001.1

Accessories available by separate order

HANDPIECE - SURGICAL TONGS	PAMANPIN001.1

Manufacturer's Identification

The manufacturer responsible for the product is:

Swiss & Wegman s.r.l.
Via Svezia, 8
Ponte San Nicolò (PD) ITALY

CHAPTER 2

SCOPE OF USE

Warnings

	ATTENTION: This paragraph specifically concerns safety instructions. It is recommended that particular attention be paid to reading it, and all instructions be followed.

Implant-Weld 300 is a medical device specifically designed for dental practice.

It exploits the Joule effect to produce the heat necessary to melt titanium, in order to obtain high quality welding directly within the oral cavity.

Thanks to its high capacity to transfer energy, ***Implant-Weld 300*** is able to weld very thick surfaces.

It is possible to set special parameters for welding or simply choose one of the pre-set programs.

The pre-installed programs are the results of careful laboratory tests, that perfected the parameters able to guarantee the best performance in specific conditions of use.

The manufacturer is not responsible for any direct or consequential undesirable effect due to misuse of the device. Such undesirable effects remain under the direct responsibility of the operator.

The user is strongly recommended to apply the following indications:

- The system must be installed and used according to the instructions given in this manual, with special consideration for those concerning safety.
- Any operation of modification, calibration and maintenance must be carried out by qualified staff authorized by the manufacturer.
- The electrical installation for which the device is intended must be in compliance with both IEC requirements and all local codes. The system must be connected to

ground.

- The manufacturer, the installer and the importer are responsible for safety, reliability and efficiency of the device only if all the above-mentioned conditions are fulfilled.
- The manufacturer makes available, on written request, the circuit diagrams and testing instructions for those parts of the system that can be repaired, to allow qualified staff authorized by the manufacturer to repair or test the device.

Application field

Implant-Weld 300 is an electrical device for dental use. In its normal application by a dentist, the handpiece transfers energy, in the form of electric power that converts into heat, to two parts to be welded within the patient's oral cavity.

Implant-Weld 300 has no therapeutic and/or diagnostic effect. It is a surgical device to be used in dental implant surgery.

The application field of ***Implant-Weld 300*** is dental surgery.

Implant-Weld 300 is designed to be used only by specialized dental staff in dental clinics or in health facilities.

Principle of action

This device has a very simple working principle. In order to weld two metals it uses the Joule effect, according to which the current passing through a resistance produces an energy which is completely transformed into heat equal to I x I x R x T (I is the current passing through the resistance R during time T).

The total resistance is composed by the resistance of the metals to be welded and the contact resistance between those metals. The contact resistance is much higher than the metal resistance, so that most of the power, and heat thereby, will be localized exactly on that point. Current passes through the metals by means of two electrodes that hold the metals tightly together and are connected to a discharge loop. The contact resistance between

electrodes and metals as well as the resistances characteristic of the electrodes must be smaller than the resistance between the metals to be welded so that all the power is localized on the welding point and is not dispersed along the remaining parts of the discharge loop. For this reason it is strongly recommended to keep the electrodes, the tongs and the contacts of the connecting cables clean and in a good state of maintenance.

As the total resistance is very small, it is necessary to supply high currents to produce enough energy and, thereby, enough heat to melt the metal. The current necessary to weld two metals in this way is provided by a current pulse.

Two additional important aspects must be taken into consideration: the welding surface and the duration of the energy application. If energy is supplied on a very small contact surface between metals, the energy density, defined as energy per surface unity, will be very high; as a consequence, it will be possible to localize it on a very small area and produce an important temperature increase. The size of the contact surface is not a settable parameter, but depends on the shapes of the items to be welded. The other parameter to be considered is duration. Too long a duration would allow heat to spread within the metals, as they are notoriously good conductors. The metal volume would increase, therefore the temperature necessary to melt metals would not be reached. On the other hand, too short a current pulse would not allow heat to spread enough within the metals, causing a superficial effect and a poor quality weld.

Therefore, the current pulse has been set to last enough time to assure the best possible quality of welding.

The welder can also produce a reduced current pulse, to pre-heat the materials before the actual welding current pulse is produced, in order to produce high-quality welding even with thick metals.

Benefits of intraoral welding

The use of the intraoral welder ***Implant-Weld 300*** facilitates dental implantology surgeries,

by allowing a functional and aesthetic recovery of edentulisms cases that would be incurable with other implant techniques without laborious and unpredictable bone reconstructions, often requiring a long time before permanent prostheses can be placed.
By using the intraoral welder to build structures to brace dental implants, such implants reach the best possible primary stability, an essential condition to reach osteointegration (histologically demonstrated). This sound primary stability allows also the immediate placement of temporary prostheses and of permanent prosthesis in predictable times and with reliable results.
The immediate-load method is based on implants specifically designed to hold fixed temporary prostheses, immediately after implant placement. With immediate loading systems, the patient who needs tooth extractions or fixed prostheses can have provisional fixed teeth placed in a single session. Traditional implant protocols associated with two-stage implants call for a waiting period 4-6 months, while the implants are hidden under the gum, before the implants are loaded. After that period, during which removable provisional prostheses are used, the dentist has to cut the gum again to complete the implant procedure to place the permanent prosthesis. On the contrary, cutting the gum again is not necessary with immediate-load implant protocols.
Single stage implant protocols are different. Indeed, through a minimally invasive surgery, a titanium screw is inserted with a post protruding out of the gum, in the space that used to be occupied by the tooth root. A temporary artificial tooth is applied on the post emerging out of the gum, the same place where the permanent tooth will be placed later. Single stage implant systems often can adapt to the patient's anatomy better than other systems, allowing for the solid placement of implants even in cases of atrophic bone.
Immediate loading technique implies shorter rehabilitation times, as little surgery is performed on mucous and bone tissues, thus reducing the healing period. Often one single session is sufficient to perform the whole necessary sequence, including extractions, other oral hygiene procedures and implant placement, ending with the placement of temporary

fixed teeth.

After this first session, the patient has to wait two to three months for final prostheses to be placed, with cement- and/or screw-retained implant restoration methods.

The most frequently used implant groups for immediate loading are:

- Two-piece implants composed of an endosteal part and an abutment screwed to it which allows a rehabilitation using a cemented and/or a screwed prosthesis.
- One-piece: monolithic implants composed of an endosteal screw emerging out the soft tissue with a post that allows rehabilitations with a cemented prosthesis.

Intraoral welding of a titanium bar or winged abutments to implants of either groups, at the end of the implant placement session, stabilizes the implants. Subsequently, the dentist will place the provisional teeth (screwed and/or cemented according to the implant system chosen) which will enable the patient to chew immediately (with some precautions), and almost eliminates any inconvenience in social interactions.

The titanium bar and/or wing abutments are essential to perform the immediate load because they preserves the “primary stability” of the implants, a basic condition for osteointegration. In fact, they provides each implant with an absolute stability.

The welded bar and/or the wing abutments do not just stabilize the implants, but also distribute the chewing forces on the whole implant structure. This is the reason why bracing of the implants with a welded bar and/or wing abutments allow both their immediate loading and their full functionality.

Immediate functionality accelerates peri-implant bone regeneration and improves bone reshaping and, thus, the osteointegration process (“secondary stability”).

The intraoral welder, designed for welding titanium parts, enables the implantologist to build superstructures on implants commonly used, thus achieving strength and a well-balanced distribution of masticatory loads on them.

Contraindications

	ATTENTION: This paragraph specifically concerns safety instructions. It is recommended that particular attention be paid to reading it, and all instructions be followed.

Implant-Weld 300 produces very high current pulses and consequently remarkable electromagnetic fields. However, it is suitable for use in any medical or surgical context: its emission limits widely comply with the standards imposed by regulations on electromagnetic compatibility for medical devices. However, in the absence of sufficient information about it, it is advised no to use ***Implant-Weld 300*** with patients or operators carrying pace-makers, implanted defibrillators or other electronic devices for life maintenance.

The electrodes and the intraoral tongs are made of materials usually well tolerated by most people, but it cannot be excluded that some subjects may be allergic to them.

Such metals are: Brass, Nickel, Steel AISI 316, Copper, Chrome.

It must be pointed out that the patient gets in contact with only few parts of the handpiece and for a very short time. Therefore, depending on each case, the dentist will decide whether or not to use the device, after an evaluation of the side effects, which must be tolerable and lesser than the benefits.

Side effects

	ATTENTION: This paragraph specifically concerns safety instructions. It is recommended that particular attention be paid to reading it, and all instructions be followed.

A misuse of the device can bring about unwanted side effects, sometimes dangerous.

The main side effect to bear in mind is the risk to burn soft tissues near the weld site, within the oral cavity.

This device has been designed to minimize the risk of such side effects. In any case, understanding such risks and using ***Implant-Weld 300*** properly prevent the occurrence of such effects.

The current discharge loop can only take place within the circuit formed by welding device, cables, tongs and joints to be welded. However, during the welding process the absence of other conductors within the oral cavity is recommended, to avoid the occurrence of unexpected discharge loops.

The heat produced during the welding process remains confined within the welding core and the increase of temperature along the rest of the metal is negligible. In spite of this, it is advised that patients avoid leaning their tongue on the metal joints to be welded.

The danger of spark formation in the welding phase is significantly reduced thanks to the tongs clamping force, which prevents the formation of empty spaces during the discharge phase. In fact, a reduction of metal thickness takes place because of local metal melting. If the tongs did not reduce accordingly the distance between electrode tips, empty spaces would be created between electrodes and metal. In order to continue to flow within the discharge loop, the current would form arcs, thus causing sparks.

As previously said, such risk is minimized by the tongs capability to constantly apply a strong pressure on the metals, even during the welding phase. However, the operator is well advised to verify that mucous membranes, soft tissues or suture threads are not pinched between metals and electrodes.

Another element to take into consideration is the choice of proper welding parameters. Exceedingly high power levels, passing through thin metals, could cause the whole metal to be melted instead of welded, thus resulting in metal splitting and spattering of molten metal pieces within the oral cavity.

The choice of welding parameters is simplified by using the preset programs. However, the

operator is advised to make some extra-oral welding tests to select the most appropriate parameters for the kind of implant and bar used.

	ATTENTION: It is possible to use preset welding parameters, but the operator is encouraged to make some extra-oral welding tests to select the most appropriate setting for the kind of implant and bar and/or wing abutment used.

CHAPTER 3

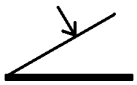
LABELS

Permanently affixed to the device are the following labels, clearly visible during operation, maintenance and repair of the equipment.

Label 1 - Handpiece

A reminder label representing the tong-shaped handpiece is placed exactly on the point where the connecting cables must be inserted.
Label size: (15 x 6 mm)

Label 2 - Pedal Connector



A label is placed to indicate the exact position where the control pedal must be connected.
Label size: (10 x 10 mm)

Label 3 - Conformity Mark

Swiss & Wegman s.r.l.
Mod. **Implant-Weld 300**
Cod. PASEOEWD001.1 S/N. 091220-A
230VAC-10W Fuse: T2.5A
Class I-BF
CE
0476 Made in Italy

An identification label is positioned on the back side of the device.

Label size: (60 x 30 mm)

Label 4 - Storage Conditions

STORAGE CONDITIONS
Temperature: 5º-50º C
Humidity: 30-90%
CE
0476

A label indicating the storage conditions is positioned on the top part of the case.

Label size: (105 x 45 mm)

CHAPTER 4

WARNINGS

Requirements for electromagnetic compatibility

	ATTENTION: This paragraph specifically concerns safety instructions. It is recommended that particular attention be paid to reading it, and all instructions be followed.

The compliance with regulations on electromagnetic compatibility is important to warrant the safety of devices and systems, since electromagnetic phenomena with different intensity levels occur in the location where the devices are usually used.

Implant-Weld 300 must be installed and set according the EMC (Electromagnetic Compatibility) standards listed in this handbook.

	ATTENTION: Portable and mobile RF communication equipments could affect the operation of the device.

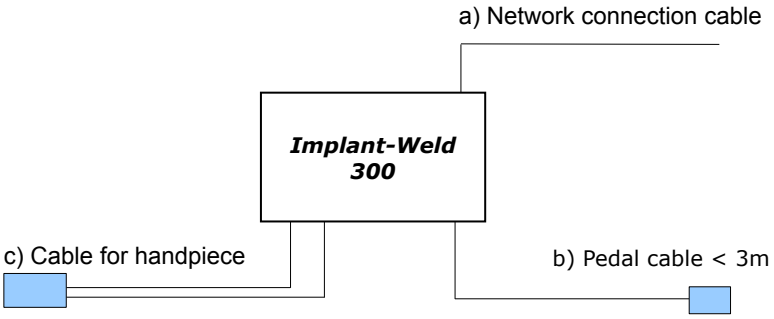
	ATTENTION: **Implant-Weld 300** is not to be used near nor lain upon or under other devices.

Position and size of the cables

A Network connection cable: 3 x 0.75 mm

B Pedal cable: coaxial cable 1 x 0.25 mm + sleeve < 3 m

C Cable for handpiece: 1 x 16 mm + 1 x 16 mm



⚠	ATTENTION: Do not use cables and accessories different from the ones indicated. It is strongly recommended to use only the cables and accessories supplied by the manufacturer. The use of any other cable can cause malfunctioning of the device, an increase of emissions or a decrease of immunity.

Emissions

Guide and manufacturer's declarations - Electromagnetic emissions		
Implant-Weld 300 is intended for use in the electromagnetic environment specified below. The customer or the user of the system should assure that it is used in such an environment.		
Emission Test	**Compliance**	**Electromagnetic environment - guide**
RF emissions CISPR 11	Group 1	Implant-Weld 300 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	Implant-Weld 300 is suitable for use in all locations, including domestic environments and those directly connected to the public low-voltage power network that supplies buildings used for residential purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage Fluctuation/ flicker emissions IEC 61000-3-3	Compliant	

Immunity

Guide and manufacturer's declarations - Electromagnetic immunity			
Implant-Weld 300 is intended for use in the electromagnetic environment specified below. The customer or the user of the system should ensure that it is used in such an environment.			
Immunity Test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - Guide**
Electrostatic discharge (ESD) IEC 61000-4-2	6 kV at contact 8 kV on air	6 kV at contact 8 kV on air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic materials, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	2 kV for power supply lines 1 kV for input/output lines	2 kV for power supply lines 1 kV for input/output lines	Network power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	1 kV differential mode 2 kV common mode	1 kV differential mode 2 kV common mode	Network power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycles 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	<5% UT (>95% dip in UT) for 0.5 cycles 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	Network power quality should be that of a typical commercial or hospital environment. If the user of the system needs continuous operation during power blackouts, it is recommended that Implant-Weld 300 be powered from an uninterruptible power supply (UPS) or a battery.
Network frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Network frequency magnetic fields should be at levels normal for a typical residential or commercial environment.
Note: UT is the a.c. network voltage prior to application of the test level.			

Electromagnetic immunity

Guide and manufacturer's declarations - Electromagnetic immunity			
Implant-Weld 300 is intended for use in the electromagnetic environment specified below. The customer or the user of the system should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - Guide**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of Implant-Weld 300, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2 \sqrt{P}$ $d = 1.2 \sqrt{P}$ from 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ from 800 MHz to 2.5 GHz where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
Notes: (1) At 80 MHz and 800 MHz, the higher frequency range applies. (2) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
A) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radios, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an			

electromagnetic site survey should be considered. If the measured field strength in the location in which Implant-Weld 300 is used exceeds the applicable RF compliance level above, Implant-Weld 300 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating Implant-Weld 300.

B) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

Recommended separation distance between portable and mobile RF communication equipments and Implant-Weld 300

Implant-Weld 300 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of Implant-Weld 300 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipments (transmitters) and Implant-Weld 300 as recommended below, according to the maximum output power of the communication equipment.

Rated maximum output power of transmitter (W)	**Separation distance according to transmitter frequency (m)**		
	From 150 kHz to 80 MHz d=1.2 √P	From 80 MHz to 800 MHz d= 1.2 √P	From 800 MHz to 2.5 GHz d= 2.3 √P
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
Notes:
(1) At 80 MHz and 800 MHz the separation distance for the higher frequency range applies.
(2) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Recommended separation distances - Examples

General Risks

	ATTENTION: This paragraph specifically concerns safety instructions. It is recommended that particular attention be paid to reading it, and all instructions be followed in order to avoid fire or explosion risks.

Intrinsic features of the device may present fire or explosion risks in case of misuse. It is recommended to follow these simple rules:

- Never use flammable gases while using the device.
- Any flammable solvent or solution must be evaporated before using the device.
- Avoid using potentially flammable anesthetics or gases such as oxygen and nitric oxide. The saturation of oxygen may set fire to some kinds of materials such as cotton or cotton-wool, if exposed to sparks produced by the electric discharge. Besides, it is important that all flammable solutions used normally for disinfection be evaporated before using the device.

CHAPTER 5

MODE OF USE

Installation

During transportation and installation the device must be handled very carefully: it is recommended that the requirements here described be fulfilled.
The first operations to perform are: arranging the place to position the equipment, checking the parts received and installing the device.

Place of use

It is advised that the room intended for use be cleared out of any extraneous material. The location should be clean and tidy.
Implant-Weld 300 can be installed on a table or an appropriate tray attached to the dental chair unit. The supporting surface must be stable, resistant, without dips, disconnections or cracks.
Verify that the electrical system be installed correctly according to the regulation standards and be connected to ground. Check that the electrical power supply complies with the device electrical requirements; in particular, the network voltage, the available power and the network frequency must be in accordance with the specified technical features of the device.
The equipment must be placed at a safe distance from other devices with which electromagnetic interference may occur.
Do not place the equipment in direct contact with walls or objects that could obstruct the natural air flow.
The environment must be maintained at a temperature between 10º and 35ºC, and humidity between 30 and 90%.

Device handling

The whole package containing Implant-Weld 300 and its accessories weighs about 7 kg. Therefore, adequate personnel is required for unloading and transporting the equipment.

	ATTENTION: The manufacturer disclaims all responsibility in case of noncompliance or deficiency in following all precautions advised for loading, unloading and handling the device and its accessories.

Check upon delivery

Upon delivery it is important to check the integrity and completeness of the material in the presence of the carrier. In particular, it is necessary to check:

- The number of packages and their correspondence with the related codes.
- The external packaging conditions and possibly the presence of damaged internal parts.
- The package contents compared with the attached packing list.

It is important to point out immediately to the carrier any nonconformity found upon checking the delivery, or sign an acceptance of the goods under reserve. In accordance with national and international laws, goods are transported at customer's risk. Besides, the goods are always shipped without insurance coverage, unless clearly specified in the contract.

Package contents

The following items will be found inside the package:

1. An intraoral welder - Model Implant-Weld 300
2. A control pedal
3. A network connection cable
4. Welding tongs
5. Two fuses
6. The user's manual (to be read carefully before any operation).

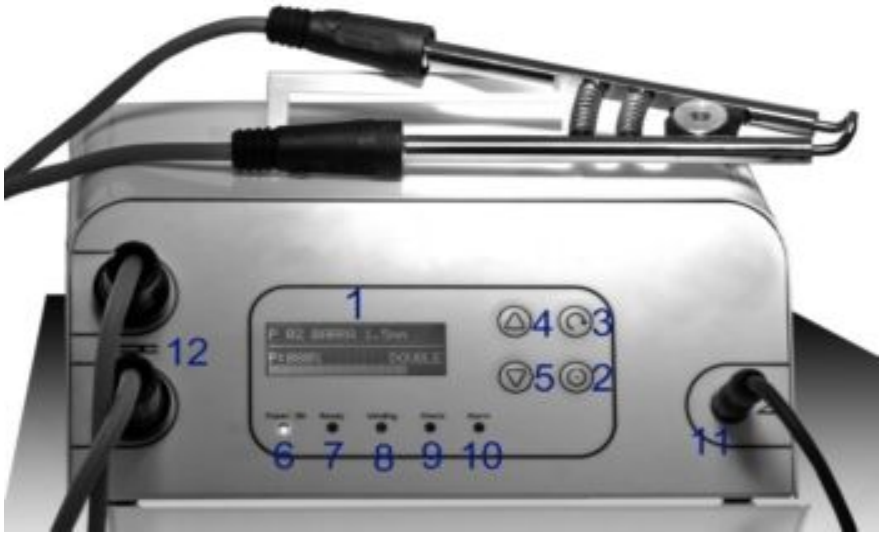
Subsequent handling

If handling or shipping of the equipment is needed, it is recommended to follow these instructions scrupulously:

- For shipment use the packaging material provided with upon delivery.
- Be sure that the master switch is turned off.
- Disconnect all cables from the main case, especially the network connection cable.
- Keep the device packed in a dry place with a temperature between 5º and 50ºC and humidity between 30 and 90%.

Main elements

Front face

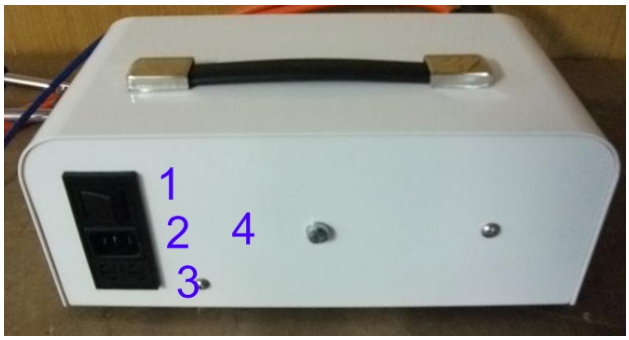


On the front face of the device the following elements can be observed:

1. Main liquid crystal display.
2. Wait / Ready buttons, identified with the symbol
3. Button to select the parameter modification, identified with the symbol
4. Button to increase the selected parameter, identified with the symbol
5. Button to decrease the selected parameter, identified with the symbol

6. Power on led light, identified with “Power ON”.
7. Ready status led indicator, identified with “Ready”.
8. Status verification led indicator, identified with “Welding”.
9. Alarm status led indicator, identified with “Check”.
10. Error status led indicator, identified with “Alarm”.
11. Socket for the pedal connector, identified with the symbol 
12. Two connectors to insert the cables of the handpiece.

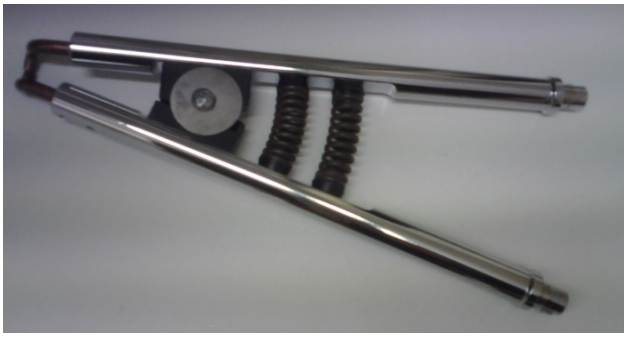
Back face



On the back face we can observe:

1. Master switch.
2. Connector for network power socket.
3. Power fuses 2 x T2.5 Ampere.
4. Identification label.

Intraoral tongs



Pre-operative sequence

Take all components out of the packaging and lay them on a horizontal surface. Remove all plastic wrappings from the components.
Keep all wrappings and packaging available for any future handling of the device.

Arrangement and connection of the handpiece

1. Insert the electrodes on the ends of the tongs and fasten them by tightening the setscrews. The two electrodes must be inserted as shown in the picture.
2. Connect the cables of the handpiece to the tongs by inserting the female connector in the proper connector and rotate it clockwise until completely locked.
3. Connect the other cable end to the device by inserting the male connector in the proper connector and rotate it clockwise until completely locked.

	ATTENTION: On delivery, the tongs are provided within an nonsterile wrapping. The tongs must be sterilized before use.

Installation of equipment

1. Insert the pedal connector in the proper socket located on the front face of the device.
2. After checking carefully the network connection cable integrity, connect it to the proper power socket placed on the back face of the device, just pressing it lightly.
3. Before such operation, make sure that the network connection cable is disconnected from the power system.
4. Check that Implant-Weld 300 is switched off and connect the network connection cable plug to the network socket.

	ATTENTION: Make sure that the network socket has an efficient ground connection. Make also sure that it is compatible with absorption standards indicated in the specifications.

	ATTENTION: Do not use any adapter nor multiple sockets of any kind.

	ATTENTION: Be sure that the electrical network complies with the regulation standards and is well connected to ground.

	ATTENTION: Check that electrical network complies with the electrical requirements of the device. In particular, it should be verified that the network power is in accordance with the specified technical features of the device, in its availability and frequency.

Now ***Implant-Weld 300*** is installed and ready to be used.

Operation sequence

Before switching on for the first time, wait at least two hours until the device temperature is adapted to the room temperature.

Switch on the back button. The switch-on status is signaled by a green light, corresponding to the label “Power ON”.

The main display will show the software version for a while, then it will ask for a password.

Password
The Implant-Weld 300 password consists in a combination of four keys chosen between “UP” and “DOWN”. The pre-set value is “UP” “UP” “UP” “UP”. It means that on first start, “UP” key must be pressed four times to insert the password. If a wrong password is inserted, the device will ask for it again. As soon as the device recognizes the correct password, it will wait for five seconds while, if the password is to be changed, the “CHANGE” key must be pressed. Then, the display will ask for the new password that may be recorded pressing a combination of four keys, choosing between “UP” and “DOWN”. After the sequence has been keyed in, press and keep on pressing the “CHANGE” key to memorize it. Once the correct password is inserted, the last program used will be displayed. If it is the first start, the first program of the list will be displayed.

Program selection

By pressing the “CHANGE” key, the “program” parameter will flash on, indicating that such parameter is now active. By pressing the “UP” and “DOWN” keys, it is possible to scroll through all programs, stopping at the chosen one. As the programs are scrolled, their related parameters are displayed.

Welding power modification

Once a treatment has been selected, all related parameters are set automatically.
It is suggested to use the pre-set parameters but, if the user decides to change power parameter, it is sufficient to press the “CHANGE” key until the power parameter flashes to indicate that such parameter is now active. Then, use the “UP” and “DOWN” keys to set the value required. Power can be set up from a min. of 20 J to a max. of 200 J.

Welding mode modification

Once a program has been selected, all related parameters are set automatically.

It is suggested to use the pre-set parameters but, if the user decides to change the emission mode parameter, it is enough to press the “CHANGE” key until the related parameter flashes to indicate that such parameter is now active. Then, use the “UP” and “DOWN” keys to set the required value.
It is possible to select 2 modes:

- SINGLE: one welding pulse
- DOUBLE: the welding pulse is preceded by a current pulse (equal to a quarter of the welding power) to pre-heat the joint to be welded.

Device activation

Once the required parameters have been selected, press the “READY” button to switch the device to the “ready” status. On pressing the “READY” button, the ready status indicator will light up with red. Position the handpiece on the spot to be welded.
Press the pedal switch to trigger the current discharge.

Positioning the handpiece

The handpiece consist of a pair of tongs on whose ends are two copper electrodes.
The electrodes can easily be inserted in the oral cavity thanks to their shape.
The handpiece has been designed to apply high pressure with the electrodes in order to hold the metals to be welded in the correct position before and during the welding process.
Before starting the welding phase through pedal pressure, it is necessary to make sure that the tongs are correctly placed and steady. When pressing the pedal, welding does not occur immediately because it is preceded by a phase of power charge before the discharge release. During this time a beep will be heard. The welding process is over only when the light signal turns off.
Do not move nor take off the tongs from their welding position until the beep stops

sounding. In “double” emission mode, where the welding pulse is preceded by a pre-heating pulse, this phase lasts longer because it consists in two charge phases and two discharge phases. Anyway, the welding process takes from 0.5 to 2.5 seconds.
When the welding phase is over, it will not be possible to repeat it for 5 seconds. The device's internal microprocessor inhibits the use of the pedal to prevent unintentional activation of the welding process. Indeed, 5 seconds are considered as the minimum time needed to remove and reposition the tongs.

Errors and alarms

Errors indicate a malfunction of the device. In case any ERROR occurs, turn the device off and turn it on again. If the problem persists, contact the manufacturer.
Alarms indicate that the device is being used under conditions not allowed.

ERRORE ELETTRICO= ELECTRICAL ERROR	Indicates malfunction of the internal circuit board.	Switch off the device, wait for thirty seconds and turn it on again. If the problem persists, take note of the error code that follows “errore elettrico”. Contact the manufacturer and reference such code.
ERRORE DI TEMPERATURA= TEMPERATURE ERROR	It indicates that the device temperature is not adequate for use.	Stop using the device and and wait at least 15 minutes before starting to use it again. Shouldn't such measures solve the problem , please contact the manufacturer.
ALLARME PINZA APERTA= ALARM OPEN TONGS	If the tongs are open or badly tightened when the welding starts, such alarm is produced.	Be sure that tongs are not open or the contact point between electrodes and metals to be welded is clean.

Tong sterilization

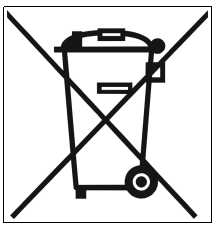
All pieces that may get in contact with the patient's organic parts can and must be sterilized.
The equipment pieces that can be sterilized are:

- tongs
- electrodes

⚠	ATTENTION: Components requiring sterilization must be always properly separated and prepared by removing any solid organic residue.

To sterilize the parts listed above it is suggested to use the standard autoclave sterilization (134ºC for 20 minutes).
Since the number of sterilization cycles in autoclave is limited, the operator is advised to check carefully the sterilized pieces after every cycle in order to verify their integrity. Specifically, verify that they do not have any scratch, break or modification to dimensions, structure or color.
In case of any damage or doubt about the integrity of a component, replace the piece immediately.
In any case, it is advisable to replace tongs and electrodes after 200 sterilization cycles.

Important notes on waste disposal



INFORMATION FOR USERS
In accordance with article 13 of Law Decree No. 151 dated 25 July 2005 "Enforcement of directives 2002/95/EC, 2002/96/EC and 2003/108/EC, related to reduction of dangerous substances in electrical and electronic devices, and to waste disposal":

- The symbol of the crossed-out rubbish bin shown on the device or on the wrapping indicates that the product must be collected separately from other waste at the end of

its useful life. It is forbidden, then, to dispose of this equipment like any other urban waste.

- The user who needs to dispose of the "used or disused" device may contact a waste collection center for waste electrical and electronic equipment, or give it back to his distributor upon buying a new one.
- The proper differentiated waste collection of the disused device followed by its recycling, processing and proper disposal helps to avoid negative side effects on environment and health, and favors the reuse and/or recycle of the materials the device is made of.
- Unauthorized waste disposal of the device by its holder implies administrative sanctions according to the applicable law.
- For further details, please see the law mentioned above.

CHAPTER 6

PREVENTIVE AND CORRECTIVE MAINTENANCE

Upon written request, the manufacturer makes available the circuit diagrams and test instructions for those parts of the system that are considered serviceable, to enable qualified staff authorized by the manufacturer to repair or test the device.

Corrective maintenance

The manufacturer strongly suggests to prevent improperly trained personnel from repairing the device. It is advised to fill in the enclosed form for technical service request and send it to the manufacturer.

Any user who intends to repair the device on his own assumes all responsibility for any possible damage to device, patients, operators or any other person. Besides, it is advised:

- to contact the manufacturer in any case to communicate the intended repair
- to replace the components considered defective with equal ones, not with equivalent ones
- after repairing, to perform all tests for preventive maintenance
- to perform an electrical safety verification.

Technical service request

Product name_____ Code_____

_____ S/N_____

Purchaser_____

Address _____

Date_____

Contact person _____ Tel./e-mail_____

Place of departure

(address)_____

Place of delivery

(address)_____

Brief description

of the problem: _____

_____

_____

Frequency_____

Date_____ Signature_____

Fill in the blanks according to the following instructions:

PRODUCT: Indicate the product name as shown on the label attached to the back face of the device.
CODE: Indicate the code as shown on the label attached to the back face of the device.
S/N: Indicate the S/N as shown on the label attached to the back face of the device.
PURCHASER: Indicate the company name of the buyer as written on the invoice.
ADDRESS: Indicate the buyer's address.
DATE: Indicate the date of the delivery note that accompanied the shipment
KEY PERSON: Indicate the contact person's name and surname
PHONE/E-MAIL: Indicate the contact person's phone number and/or e-mail.
DEPARTURE PLACE: Indicate address of the place where the device is presently.
DELIVERY PLACE: Indicate address of the place where the device must be delivered after technical service has been made. Addressee, Street, ZIP code, City, State.
BRIEF DESCRIPTION OF THE PROBLEM: Write a brief description of the problem indicating conditions under which it first occurred. Furthermore, indicate whether or not the product can still be used.
FREQUENCY: If applicable, indicate how often the problem happens (ex.:it suddenly turns off once a day)

Preventive maintenance

Yearly, and whenever it is considered appropriate, it is advised to perform the following procedure to check the correct function of the equipment and prevent any breakage:

- Unplug the network connection cable.
- Check if the case is in a good condition, without signs of damage such as rust, paint scratches, dents, breakages, cracks.
- Open the upper cover by unscrewing the 4 side screws and lay the cover aside, being careful not to stretch excessively the cables that connect the upper cover to ground.
- Remove any dust from the inside by using compressed air.
- Do not touch any internal parts.
- Check that the wiring is in good condition, without any sign of damage or blackening.
- Reposition the cover and close the device.
- Check that all labels are in good condition, by comparing them with those illustrated in this handbook.
- Check that the network connection cable is in a good state without any sign of breakage or wear.
- Test the protection cable continuity.
- Connect the network connection cable to the unit and to a 220 V AC socket.
- Connect the control pedal.
- Turn on the device without connecting the handpiece.
- Enter the password.
- Keep the “DOWN” key pressed.
- A test on display and on light indicators will start. Check that the indicators are working and in good condition.
- During this test all the main displays: “READY”, “CHECK” and “ALARM”

indicators will light up in sequence, while the “POWER ON” indicator of presence of power will be lit up with green throughout all the test. “Charging” indicator will be off.

- When the test is over, a beep will sound and the device will turn on normally.
- Select a treatment.
- Press the “READY” key.
- Press the control pedal.
- The device should show ALLARME PINZA APERTA=ALARM OPEN TONGS.
- Connect the handpiece equipped with tongs and put it in the rest position with electrodes in contact.
- Press “READY” key: the system indicates “to conclude the welding process” without signaling any error.
- Execute an electrical safety test for CLASS I devices with a BF handpiece.
- Inform manufacturer about any abnormal condition.

The only elements subject to wear are:

- The power accumulator capacitor must be replaced after 3 years of use.
- The EEPROM internal memory can perform at most 1,000,000 cycles of writings. Working 8 hours a day, it is expected to last more than 5 years. After this time, it is necessary to replace it.

CHAPTER 7

SPECIFICATIONS

Label data			
Manufacturer	SWISS & WEGMAN s.r.l.		
Model	Implant-Weld 300		
Power supply	230V AC		
Network frequency	50-60 Hz		
Input average power	10 W		
Maximum peak power (during welding phase)	1 KW		
Medical Device Class	2 B		
Insulation Class	I - Handpiece Type BF 		
Protection against anesthetic	Equipment not suitable for use in the presence of a flammable anesthetic mixture with oxygen or nitrous oxide.		
IP degree of protection	IPXO		
Mode of use	Continuous operation		
Working conditions Temp./RH/Press.	10ºC - 35ºC	30%-90%	700-1100 hPa
Storage conditions Temp./RH/Press.	5ºC - 50ºC	30%-90%	700-1100 hPa
External connections	Pedal		
Size	30x22x17 cm (length x width x height)		
Weight	About 7 kg		

Main parameters	
Power	20J – 300J
Emission mode	Selectable: Single - Double pulse
Time between two pulses	5s
Mode of use	Continuous
Welding power stability	±20%

CHAPTER 8

LIABILITY FOR DEFECTIVE PRODUCTS

We guarantee to our customers that on purchase the device and its accessories do not have any defect and that, being it a device for professional use, should any malfunction occur during the first year from purchase date, it will be covered by warranty.
The warranty is not applied to any defect, damage or breakdown due to misuse, wrong maintenance, negligence or noncompliance with the dictates of the user's manual.
Our warranty does not include support to repair any damage resulting from handling by unauthorized personnel.
In order to get a repair/replacement under warranty, it is necessary to communicate the defect in advance by fax, letter or e-mail, sending the form “Technical Service Request” properly filled up.
The request will be verified by our technical staff and, in case it is an intervention covered by warranty, the most suitable manner for providing support will be communicated.
The warranty includes all costs of labor and any repaired or replaced part that our technical staff considers to be the cause of the defect found, provided that such defect is not due to the user's negligence, as mentioned above.
The warranty excludes all costs due to replacement of components subject to wear. Such components are listed in the section of the user's manual concerning maintenance procedures.
The equipment may be repaired or replaced depending on cost effectiveness.
Transport or shipment of defective equipment from the user's premises to the technical support premises will be at the customer's expense, including any transport insurance cost. Therefore, warranty does not cover any shipment and round-trip freight charges.
In case of delivery by mail, railway or courier, it is recommended to use the original packaging. The Customer will be responsible for making sure the goods do not suffer

damage during transportation.

Our warranty does not cover any damage due to transportation.

No responsibility is accepted, nor compensation to customer is provided, for any damage or contingency, direct or consequential, accidental or resulting from lack of use during the time between defect detection and restoration of the device.