JUVA+
INJECTION SYSTEMS

DEVICES DESCRIPTION

The Denta®Pen
The Denta®Pen is a new cordless and motorized injection system powered by a lithium battery.
The Denta®Pen is a non-sterile device intended to assist medical practitioners in injecting dental anesthesia.
After inserting the anesthesia cartridge into the Cartridge holder (DentaLink), the practitioner simply presses the top part of the DentaLink for a smooth and even delivery of the product in continuous flow mode.
The Denta®Pen Pen is only intended for dental anesthesia injections.

The DentaLink
The DentaLink is a cartridge holder that has been designed to improve ergonomics, allowing the user to have greater freedom to operate during injections.
The DentaLink is compatible with most anesthesia cartridges on the market.
The DentaLink is compatible with needles.
The DentaLink is compatible exclusively with the Denta®Pen.
Do not touch the key board while inserting the battery cap to the Denta®Pen.

PRECAUTIONS AND RECOMMENDATIONS

Precautions for use
Please read the following instructions carefully and follow the proper safety measures in order to perform a successful injection:

- Only a qualified and experienced medical practitioner should use the Denta®Pen.
- The use of the Denta®Pen and the results thereof are the exclusive responsibility of the practitioner.
- The practitioner is the only one who can evaluate the indications and contraindications relative to the technique to employ, the anesthesia to be administered and the appropriate needle to use.
- In all cases, the medical practitioner shall proceed only after having fully familiarized himself or herself with both the product and its educational material, including their instructions for use.
- The DentaLink (cartridge holder) is for a single patient and a single session use only.
- Do not use if the package is opened or damaged.

Adverse reactions and contraindications
It is the practitioner's full responsibility to read and follow those Instructions for use in order to avoid any adverse reactions or complaints.
Possible sides effects and contraindications can result from the use of products in conjunction with the Denta®Pen (e.g anesthesia cartridge, needle, etc.). It is the practitioner's full responsibility to check and follow the instructions for use of any products used with the Denta®Pen.

General recommendations

- Keep the Denta®Pen out of reach of children, it is for professional use only.
- The equipment cannot be used where there is an inflammable mixture of air, oxygen or nitrogen.
- Store the Denta®Pen away from heat and sun exposure.
- Keep the Denta®Pen away from water and chemical products.
- Always check whether the device is functioning properly before use.
- If the On/Off light turns orange, change the battery.
- The Denta®Pen turns off automatically, when not in use, after 4 minutes.
- The cartridge holder (DentaLink) is designed for use with the Denta®Pen exclusively and therefore cannot be used with any other third party device.
- Do not sterilize the following components: Denta®Pen and battery.
- Wearing single-use gloves is highly recommended for the use of the equipment.
- No alteration of this equipment is allowed.
- Dispose of the DentaLink (cartridge holder) or battery according to your local environmental regulations.
- The battery used in this device may present a fire or chemical burn hazard if mistreated. Do not open battery, dispose of in fire, put in backwards, mix with used or other battery types, short circuit, disassemble, heat above 100°C (212°F), or incinerate.
- The device emits electromagnetic radiation at levels inferior to the limits recommended by the pertinent laws and regulations in force. Please refer to the EMC information section.
- Do not use the Denta®Pen near electronic equipment which emits electromagnetic fields. Portable and mobile RF communications equipment can affect the Denta®Pen.

ACCESSORIES

Battery cap
Button Battery Lithium 6V /170 mAh
The Denta®Pen must be used with a certified battery IEC60086-4 only

DentaLink
DentaLink (cartridge holder): PEEK

CLEANING

Between uses, appropriate care should be taken to ensure that the Denta®Pen is clean.

After each use, the physician shall:

1) Remove the needle, the cartridge and the cartridge holder
2) Press the return button (so the lead screw goes to its original configuration)
3) Wipe carefully the Denta®Pen with a damp cloth and a 1:100 dilution of 5.25%-6.15% sodium hypochlorite to remove visible organic residue (e.g., residue of blood) and inorganic salts.

Warning:

- Clean the Denta®Pen as soon as practical after use.
- Do not immerse or soak the Denta®Pen in liquids.
- Do not use an automatic washer to clean the Denta®Pen.
- Inspect Denta®Pen surfaces for breaks in integrity that would impair cleaning. Do not use a Denta®Pen that no longer functions as intended or cannot be properly cleaned.

HANDLING CONDITIONS

It is recommended to store and transport the Denta®Pen in its original packaging.
OPERATING CONDITIONS 0 - 2000 m
Temperature: 20°C TO 25°C
Humidity: 60% RH AT 30°C non-condensing

TRANSPORT CONDITIONS
Temperature: -20°C TO 40°C
Humidity: 60% RH AT 30°C non-condensing

STORAGE CONDITIONS
Temperature: -20°C TO 40°C
Humidity: 60% RH AT 30°C non-condensing

ASSEMBLY AND USE

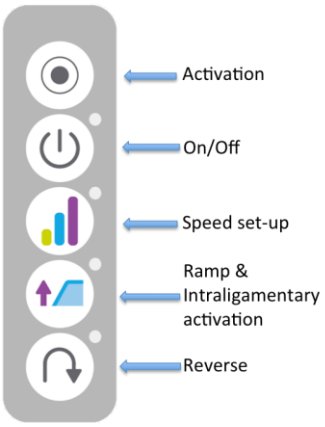
1) Insert the cartridge into the DentaLink.
2) Connect the Dentalink to the main body.
3) Rotate the assembly counter clockwise to lock it onto the Denta®Pen.
4) "Click" indicates the proper attachment of the DentaLink to the Denta®Pen.
5) Attach the needle into the cartridge holder.
6) Rotate the cartridge holder to orientate the needle as wished.
7) Press the ON/OFF button. The green light indicates that the device is switched ON.
8) Select the ramp mode and set-up the delivery speed.
9) The injection can be performed by pressing the top of the DentaLink.

After the use

1) Once the injection is over, replace the needle protection.
2) Rotate the DentaLink clockwise to release it from the Denta®Pen, along with the cartridge and needle.
3) Discard the cartridge and the needle.
4) Press the reverse button to return the lead screw to its original position.

The Device Control Buttons and Control Lights

- Activation Button
- Device ON/OFF button and light indicator
- Continuous flow mode speed setup button and light indicator
- Ramp & intraligamentary activation button and light indicator
- Original position screw button and light indicator



WARRANTY

The warranty period for the Denta®Pen is 18 months from the date of purchase.

LEGEND

	Manufacturer
	Manufacturing date
LOT	Lot number
SN	Serial number
REF	Catalog number
	Caution, consult documents
-20°C +40°C	Temperature limitation (-20°C/+40°C)
NON STERILE	Non-sterile
	Read usage instructions
	Keep dry
	Do not expose to sunlight
	Type BF applied part
IP00	No Protection against ingress of solid and liquid
	Do not throw away

CE 2460

Juvaplus SA
Rue Maladière 71C
CH-2000 Neuchâtel
SWITZERLAND

P3.23aR2

EMC Information

Medical electrical equipment should be used with precautions according to EMC, and must be installed according to the EMC notices disclosed in this manual.

Table 1 – Guidance and manufacturer's declaration – Electromagnetic emissions – for all ME equipment ad ME systems		
The Denta®Pen is intended for use in the electromagnetic environment specified below. The customer or the user of the Denta®Pen should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	**Group 1**	Denta®Pen 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**	The Denta®Pen is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	**Not applicable**	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	**Not applicable**	

Table 2 – Guidance and manufacturer's declaration – Electromagnetic immunity – for all ME equipment ad ME systems			
The Denta®Pen is intended for use in the electromagnetic environment specified below. The customer or the user of the Denta®Pen should assure that it is used in such an environment.			
Immunity test	**IEC60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, 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	**Not applicable**	Mains power quality should be that of a typical commercial or hospital environment. Denta®Pen is a self-powered (non-rechargeable battery) handy device that is not connected to the public low-voltage power supply network.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	**Not applicable**	Mains power quality should be that of a typical commercial or hospital environment. Denta®Pen is a self-powered (non-rechargeable battery) handy device that is not connected to the public low-voltage power supply network.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % *U*T (>95 % dip in *U*T) for 0,5 cycle 40 % *U*T (60 % dip in *U*T) for 5 cycles 70 % *U*T (30 % dip in *U*T) for 25 cycles <5 % *U*T (>95 % dip in *U*T) for 5 s	**Not applicable**	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Model Denta®Pen requires continued operation during power mains interruptions, it is recommended that the Denta®Pen be powered from an uninterruptible power supply or a battery. Denta®Pen is a self-powered (non-rechargeable battery) handy device that is not connected to the public low-voltage power supply network.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Table 4 – Guidance and manufacturer's declaration – Electromagnetic immunity – for ME equipment and ME systems that are not life supporting			
The Denta®Pen is intended for use in the electromagnetic environment specified below. The customer or the user of the Denta®Pen should assure that it is used in such an environment.			
Immunity test	**IEC60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	Not applicable	Portable and mobile RF communications equipment should be used no closer to any part of the Denta®Pen, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended Separation Distance d = (3,5/V1) √P2 d = 1.17 √P2 80 MHz to 800 MHz d = 2.33 √P2 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 meters (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: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3V/m	

Table 6 – Recommended separation distances between portable and mobile RF communications equipment and the Denta®Pen		
Denta®Pen is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Denta®Pen can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and Denta®Pen – as recommended below, according to the maximum output power of the communications equipment.		
Rated Maximum Output Power of Transmitter (W)	**Separation Distance According to Frequency of Transmitter (m)**	
	80 MHz à 800 MHz d = 1.17 √P	800 MHz à 2,5 GHz d = 2.33 √P
0.01	0.12	0.23
0.1	0.37	0.74
1	1.17	2.33
10	3.7	7.37
100	11.70	23.30