osstell CLASSIC

INSTRUCTIONS FOR USE

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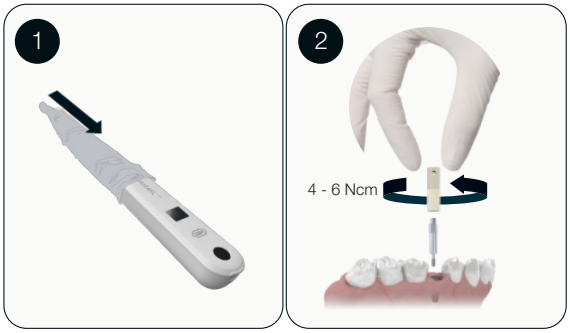

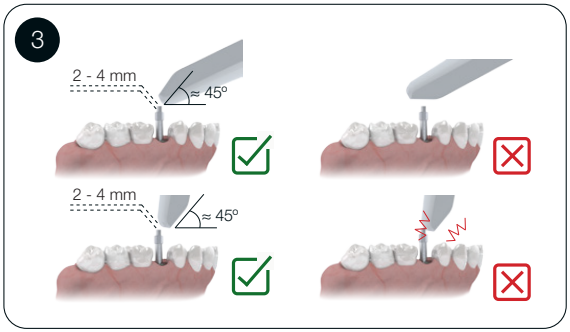

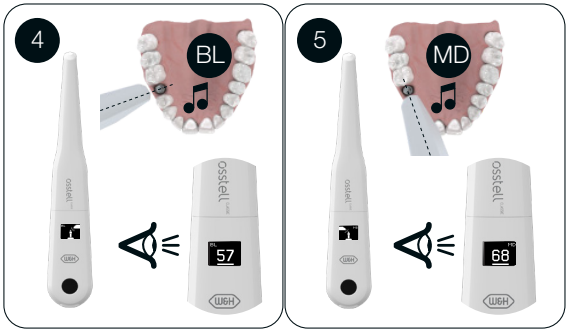

osstell CLASSIC

Languages

Welcome

Congratulations on the purchase of your new Osstell Classic.
Before you start using your instrument, please read through the entire instructions for use.

Table of content

1) Introduction

Qualifications of the user

This medical device is intended to be used by qualified dentists, doctors, surgeons, or specialist staff appointed by the responsible clinician.

Responsibilities of the user

Read through the entire instructions for use before using this device.

Observe the warnings and precautions.

Any serious incident that has occurred in relation to the medical device should be reported to the manufacturer and the competent authority!

Responsibility of the manufacturer

The manufacturer can only accept responsibility for the safety, reliability and performance of the medical device when compliance with the following instructions is ensured:

- The medical device must be used in accordance with these instructions for use.
- Modifications or repairs may only be undertaken by the manufacturer.
- Unauthorized opening of the instrument invalidates all claims under warranty and any other claims.

In addition to unauthorized disassembly, modification or repair of the instrument and non-compliance with these instructions for use, improper use will void the warranty and release the manufacturer from all other claims.

2) Warnings and precautions

Warnings

⚠ Read all instructions before operating the instrument.

⚠ The instrument emits an alternating magnetic field that potentially could interfere with cardiac pacemakers! Keep the instrument away from implanted electronic devices. Do not place the instrument on the patient's body.

⚠ A transparent, barrier sleeve must be used to cover the instrument when used on patients. See section 10 for recommended sleeves and section 13 for information on recommended cleaning and maintenance.

⚠ Only use the acceptable agents listed in section 13 when cleaning and maintaining the instrument. Other agents may permanently damage the instrument enclosure.

⚠ Do not autoclave the instrument.

⚠ The SmartPeg Mount must be sterilized before use.

⚠ Always perform a measurement in two directions, Buccal-Lingual and Mesial-Distal, as guided by the instrument. This is important to detect the lowest implant stability.

⚠ The SmartPegs are disposable and should only be used for one or multiple measurements at one treatment session, for a single patient only (to avoid cross-contamination). Repeated re-use may result in false readings due to wear and tear of the soft aluminum SmartPeg threads. Do not use if the product sterile barrier system or its packaging is compromised.

⚠ Do not expose the instrument to extreme high temp, e.g. leaving it in the car dashboard on a warm sunny day.

⚠ The instrument is not protected from ingress of fluids, e.g. water, at the USB connector (IP20 classified).

⚠ Mains-operated power supplies or USB cable used for charging, shall not be reachable by the patient.

⚠ Always charge the instrument, using the supplied USB-cable, directly connected to a 5 Volt USB type A port. Splitter cables must never be used as these can lead to permanent damage to the device.

Precautions

⚠ To avoid interference with other equipment, the instrument should not be held close to electronic devices.

⚠ Do not use the instrument in the presence of explosive or flammable materials.

⚠ See section 4, 5 and 9 for information about approved and compatible accessories.

3) Intended use

The instrument is intended for use as a Dental Implant Stability Analyzer.

4) Indication for use

The instrument is indicated for use in measuring the stability of implants in the oral cavity and maxillofacial region.

Conditions

Surgically placed implants or abutments for which there is space to attach a compatible SmartPeg.

Reasons for use

The instrument can add important information to the evaluation of implant stability and can be used as part of an overall treatment evaluation program. The final implant treatment decisions are the responsibility of the clinician.

Contraindications

The instrument is contraindicated for implant systems to which the SmartPeg could not be attached for mechanical incompatibility reasons. See section 9 for more information about SmartPegs. The instrument is contraindicated when used together with Pegs not approved by the manufacturer. The instrument is contraindicated where it is not possible to attach the SmartPeg due to lack of space, or where it impinges on other artificial or anatomical structures.

5) Description

The instrument is a handheld instrument that involves the use of the non-invasive technique, Resonance Frequency Analysis. The system involves the use of a SmartPeg attached to the dental implant or abutment by means of an integrated screw. The SmartPeg is excited by a magnetic pulse from the instrument tip.

The resonance frequency, which is the measure of implant stability, is calculated from the response signal. Results are displayed on the instrument as the Implant Stability Quotient (ISQ). The ISQ is scaled from 1 to 99. It is a measurement of the stability of the implant and is derived from the resonance frequency value obtained from the SmartPeg. The higher the number, the greater the stability. The instrument software can be updated by using the supplied USB cable, type A-C.

Your system includes the following items

① Instrument ② USB cable, type A-C ③ SmartPeg Mount
④ TestPeg ⑤ Instructions for Use ⑥ Quick Guide

Applied Parts: Instrument tip and thin part of body.

6) Safety symbols

	Caution
	Follow instructions for use
	Consult instructions for use
	See section 2 warnings and precautions
	Type BF applied part
	Manufacturer
YYYY-MM-DD	Country and date of manufacture
SN	Serial number
Li-ion	Do not dispose of with domestic waste. Li-ion battery.
CE	CE mark
CE 0297	CE mark with identification number of the notified body
	Non-ionizing electromagnetic radiation
135°C	Not Sterilizable
135°C	Sterilizable up to 135 degrees Celsius
	Temperature limitation
	Humidity limitation
	Atmospheric pressure limitation
IP20	Protected against solid foreign objects of 12.5 mm Ø and greater. No protection against water.

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	Use by date
LOT	Lot/batch code
STERILE R	Sterilized using irradiation
Rx only	For US market only: Prescription use only. U.S. Federal Law restricts this device to sale by or on the order of a licensed practitioner
REF	Catalog number
2	Do not reuse
MD	Medical device
	Data Matrix code for product information including UDI (Unique Device Identification)
	Do not use if package is damaged and consult instructions for use
	Keep dry
	Keep away from sunlight
	Single sterile barrier system with protective packaging outside
	Single sterile barrier system

7) Before you start

Charge the instrument by connecting the small USB connector of the USB cable to wide end of the instrument. Connect the large USB connector to a standard USB type A port of a PC, laptop or charger.

The instrument will start-up and enter charging mode. Charge the instrument for at least 1 hour or until the instrument indicates full charge. Remove the USB cable, type A-C.

Note! It is not possible to perform an ISQ measurement during charging.

8) TestPeg

The TestPeg may be used for testing and learning how to use the system. Place the TestPeg on the table or hold it in your hand. Activate the instrument by a short press on the button and hold the instrument tip approximately 2-4 mm away from the top of the TestPeg. The instrument should start to measure and present an ISQ value of ≈ 55 +/- 2.

9) SmartPeg

The SmartPeg is available with different connection geometries to fit all major implant products on the market. You can find all available SmartPegs on **osstell.com/smartpegguide**.

The SmartPegs are disposable and should only be used for one or multiple measurement at one treatment session, for a single patient only (to avoid cross-contamination). Repeated re-use may result in false readings due to wear and tear of the soft aluminium SmartPeg threads.

10) How to measure

Prior to use on a patient, place a barrier sleeve over the instrument. The barrier sleeve helps prevent cross-contamination and helps keep dental composite material from adhering to the surface of the instrument tip and body, and discoloration and degradations from cleaning solutions.

Note

- Barrier sleeves are single patient use only.
- Discard used barrier sleeves in standard waste after each patient.
- Do not leave barrier sleeves on the instrument for extended periods.
- See below for recommended barrier sleeves.
  TIDIShield, Art no: 20808, Art no: 20987. **www.tidiproducts.com**
  PremiumPlus: 183-2 X-Ray sensor sleeve, size 2
  Please also see additional recommended barrier sleeves on: **osstell.com/support-osstell-classic**
- The instrument must be cleaned with appropriate agents after each patient. See section 13) Cleaning and maintenance for acceptable agents.
  - A first measurement should be taken at implant placement to get a baseline for future measurements throughout the healing process. Before the final restoration, another measurement is taken which makes it possible to observe the stability development of the implant.
  - It is recommended to measure in both Buccal-Lingual and Mesial-Distal direction to find the lowest stability. Therefore, the instrument prompts the user to measure in both these directions.
- We recommend studying the more detailed information (videos and quick guides) available on **osstell.com/support-osstell-classic**; to utilize the full functionality of your instrument.

1. Activate the instrument by a short press on the button. The instrument will start-up and after showing the battery status, the instrument will be ready for measurement in the BL (Buccal–Lingual) direction, which is prompted in the display.
2. Place a barrier sleeve over the instrument. **See fig 1, page 1**.
3. Place the appropriate SmartPeg for the implant into the SmartPeg Mount. The SmartPeg is magnetic, and the SmartPeg Mount will hold the SmartPeg. **See fig 2, page 1**. Attach the SmartPeg to the

implant or abutment by screwing the SmartPeg Mount using finger force of approximately 4-6 Ncm. Do not overtighten, to avoid damaging the SmartPeg threads.

4. Bring the instrument inside the mouth and hold the instrument tip close (2-4 mm) to the top of the SmartPeg without touching it. Hold the tip at approx. 45° angle towards the SmartPeg top as indicated in the display and shown with a green check mark in **fig 3, page 1**. Do not measure in the ways indicated with a red X mark in **fig 3, page 1**.
   - An audible sound indicates when a measurement has been made, and measured data will be shown in the display. **See fig 4, page 1**. Bring the instrument out of the mouth to clearly read the ISQ value.
   - The instrument will automatically switch to measure in Mesial-Distal direction as indicated in the display. **See fig 5, page 1**. **Note!** Do not bring the instrument back in the mouth until the display has switched to the next direction.
5. Repeat step 4 to measure in the Mesial-Distal direction, **see fig. 5, page 1**. The latest measurement will be presented for each direction, **see fig 6, page 1**.
   A short press on the button will reset the measured values and the instrument will be ready for measurement in the BL direction as indicated in the display, **see fig 7, page 1**.
6. When measurements in both directions are performed, remove the SmartPeg by using the SmartPeg Mount.
7. The instrument is automatically turned off after 60 seconds of no measurement or press the black button for more than 2 seconds to turn it off.

11) How to measure on an abutment

When measuring on abutment level, the ISQ values will not be equal to when measuring on implant level. They will in most cases be lower. This is due to that the total length of abutment plus the SmartPeg will be a bit different (longer) depending on abutment height used. To compensate for this there are several SmartPeg types available for abutments. You can find all available SmartPegs on **osstell.com/smartpegguide**.

Due to the different heights and angles of abutments, the ISQ could still not be equal to ISQ on implant level. It is therefore recommended that one takes an ISQ reading on implant level (using the appropriate SmartPeg for that implant) at time of implant placement and then compare that with the ISQ value taken on the abutment (using the appropriate SmartPeg for that abutment) as to compare to the ISQ on abutment level.

The ISQ on abutment level can then be used as a relative ISQ value for tracking the implant stability during the healing period.

12) Interpret the result

Implant stability

An implant can have different stability in different directions. The stability of the implant is dependent of the surrounding bone configuration. There is often a direction where the stability is lowest, and a direction where the stability is highest and these two directions are most often perpendicular to each other.

To find the lowest stability (lowest ISQ value) it is recommended to measure from two different directions. The lowest stability is in most cases found in the Buccal-Lingual direction. The highest stability is in most cases found in the Mesial-Distal direction.

The ISQ value

Assuming there is access to the implant, ISQ measurements should be performed at implant placement and before the implant is loaded or the abutment is connected. After each measurement, the ISQ values are used as the baseline for the next measurement performed. A change in the ISQ value reflects a change in implant stability. In general, an increase in ISQ values from one measurement time to the next indicates a progression towards higher implant stability while a decrease in ISQ values indicates a loss in stability and, possibly, implant failure. A stable ISQ value would indicate no change in stability. **See last page in this IFU booklet.**

ISQ values have not been correlated with other methods of mobility measurements.
Note! The final implant treatment decisions are the responsibility of the clinician.

13) Cleaning and maintenance

13.1 General (outside US)

Before each use, moisten a gauze or soft cloth with a recommended (see list below) surface cleaner and wipe the whole instrument.

Note! Do not autoclave the instrument.

Routinely check the surface of the instrument tip and overall surface for possible cracks and residuals.

Recommended cleaners

- Isopropyl alcohol 70%
- Low foaming, neutral pH, enzymatic detergents like:
  - BePro Disinfectant Wipes, REF 19500102, **www.wh.com** (can be ordered from W&H Sterilization)
  - Medizime LF
  - Enzol

Do not use

- Acidic or phenolic based cleaners/disinfectants
- Strong alkali detergent of any type, including hand soaps and dish soaps
- Bleach based cleaners
- Hydrogen Peroxide based cleaners
- Abrasive cleaners
- Acetone of hydrocarbon based cleaners
- MEK (Methyl Ethyl Ketone)
- Birex
- Gluteraldehyde
- Quaternary Ammonium Chloride salt-based cleaners

The instrument does not require regular maintenance. In the event of an instrument malfunction, contact the local sales representative or distributor for further instructions.

SmartPeg	Delivered sterile. The SmartPegs are disposable and should only be used for one or multiple measurements at one treatment session, for a single patient only (to avoid cross-contamination).
TestPeg	Is not used intraorally, does not require sterilization.

The Smartpeg Mount should be cleaned and sterilized before each use according to the instructions below.

SmartPeg Mount: Must be autoclaved according to the recommended sterilization method, validated to sterility assurance levels (SAL), according to ISO 17665-1 and ISO 17664. The SmartPeg Mount should be placed in suitable packaging for the sterilization process.

Sterilization method	Exposure temperature	Exposure time
Pre-vacuum	132° C (270° F)	4 min
Pre-vacuum	134° C (273° F)	3 min
Gravity	134° C (273° F)	10 min

Warnings: do not exceed 135° C (275° F). Drying time: 30 minutes.

Carefully inspect the SmartPeg Mount for damage or wear. Hand wash the SmartPeg Mount using a neutral instrument detergent. Rinse and dry; carefully inspect the SmartPeg Mount for damage and wear. Sterilize the SmartPeg Mount according to the autoclave manufacturer's instructions. Do not wash in dishwasher.

Store sterile goods dust-free and dry.

13.2 US specific

After each use, follow the cleaning and disinfection procedures below.

Note! Do not autoclave the instrument.
Routinely check the surface of the instrument tip
and overall surface for possible cracks and residuals.

Steps	General cleaning instruction
1	Remove and dispose of used barrier sleeve.
2	Soak cloth in Medizime LF enzymatic cleaner. Paying particular attention to critical sites noted in the figure above, wipe down the housing of the device for at least one (1) minute.
3	Visually inspect the instrument for contamination and visible debris. If contamination or visible debris is present, remove it with a soft bristle brush, cotton swab, or soaked cloth depending on location of the soil.
4	Soak cloth with distilled water. Pay particular attention to critical sites. Wipe down device for at least one (1) minute.
5	Inspect device again and repeat steps 2 and 3 if soil persist.
6	Wipe down device with soft cloth dampened with 70% IPA to help remove moisture.
7	Allow device to air dry completely before next use (minimum three (3) minutes).

Steps	General disinfection procedure
1	According to manufacturer's instructions, the minimum exposure time for the CIDEX® OPA disinfectant is twelve (12) minutes. Disinfectant application should be performed by placing the device in a cup with the tip faced down, see figure above. Fill the cup with CIDEX® OPA to a level which will allow immersion to 7.5 cm (3 inches). Leave the device immersed for a minimum exposure time of twelve (12) minutes. Upon completion of the exposure time, lift the device from the cup with the tip still faced down and use a clean cloth to manually wipe the device.
2	To remove any residual disinfectant, fill a new cup with distilled water to a level which will allow immersion to 7.5 cm (3 inches) and leave the device immersed for a minimum of one (1) minute.
3	Repeat the one (1) minute distilled water immersion two (2) additional times using fresh water for a total of three (3) rinses.
4	Following removal of the device from water immersion, thoroughly ensure disinfectant residue removal by wiping down the device with a soft cloth dampened with 70% IPA.
5	Repeat the 70% IPA wipe procedure two (2) additional times, for a total of three (3) alcohol wipes.
6	Allow devices to air dry out of exposure to direct sunlight.

The manufacturer has validated the High Level Disinfection for up to 5000 processing cycles without damage to the instrument.

Acceptable cleaning fluids

- Low foaming, neutral pH, enzymatic detergents like:
  - Medizime LF
  - Enzol

Acceptable disinfectant fluids

- CIDEX® OPA Solution

Do not use

- Acidic or phenolic based cleaners/disinfectants
- Strong alkali detergent of any type, including hand soaps and dish soaps
- Bleach based cleaners
- Hydrogen Peroxide based cleaners
- Abrasive cleaners
- Acetone of hydrocarbon based cleaners
- MEK (Methyl Ethyl Ketone)
- Birex
- Gluteraldehyde
- Quaternary Ammonium Chloride salt-based cleaners

The instrument does not require regular maintenance. In the event of an instrument malfunction, contact the local sales representative or distributor for further instructions.

SmartPeg	Delivered sterile. The SmartPegs are disposable and should only be used for one or multiple measurements at one treatment session, for a single patient only (to avoid cross-contamination).
TestPeg	Is not used intraorally, does not require sterilization.

The Smartpeg Mount should be cleaned and sterilized before each use according to the instructions below.

SmartPeg Mount: Must be autoclaved according to the recommended sterilization method, validated to sterility assurance levels (SAL), according to ISO 17665-1 and ISO 17664. The SmartPeg Mount should be placed in a FDA cleared autoclave bag such as: PeelVue – Ref# 31610, size 3.5 x 5.25 or equivalent bag.

Sterilization method	Exposure temperature	Exposure time
Pre-vacuum	132° C (270° F)	4 min
Pre-vacuum	134° C (273° F)	3 min
Gravity	134° C (273° F)	10 min

Warnings: do not exceed 135° C (275° F). Drying time: 30 minutes.

Carefully inspect the SmartPeg Mount for damage or wear. Hand wash the SmartPeg Mount using a neutral instrument detergent. Rinse and dry; carefully inspect the SmartPeg Mount for damage and wear. Sterilize the SmartPeg Mount according to the autoclave manufacturer's instructions. Do not wash in dishwasher.

Store sterile goods dust-free and dry.

14) Technical information

Technical description

The instrument is CE-marked according to MDR 2017/745 in Europe (Class I, internally powered, type BF applied parts. Not AP or APG equipment, not protected against ingress of water).

The instrument is in accordance with applicable parts of IEC 60601-1/ANSI/AAMI ES 60601-1.
The symbols used, follow the European standard EN 60601-1 and ISO 15223 as far as possible.

Notes on electromagnetic compatibility (EMC)

Medical electrical equipment is subjected to particular precautions with regards to EMC and must be put into operation in accordance with the EMC notes included below:

The manufacturer guarantees the compliance of the device with the EMC requirements only when used with original accessories and spare parts. The use of other accessories / other spare parts can lead to an increased emission of electromagnetic interference or to a reduced resistance against electromagnetic interference.

You can find the current EMC manufacturer's declaration on our website at **osstell.com/osstell-classic**, scroll down until you see a button to download **EMC DECLARATION**.

Alternatively, you can obtain it directly from your local sales representative or distributor.

Battery charging

The instrument contains a rechargeable lithium-ion battery.

The instrument should be charged using the USB cable, type A-C, directly connected to a standard USB 2.0 or 3.0, 5 Volt USB type A port. Battery status and charging is indicated in the display with a battery symbol having 4 levels: 100% (fully charged), 75%, 50% and less than 25%. When the level is less than 10%, the instrument will change the battery symbol to alert that it is time to charge the instrument.

Note! The instrument, when connected to a charger, is a Medical Electrical system. The charger shall conform to relevant EN/IEC safety standards, e.g. IEC 60950-1, IEC 62368-1 or IEC 60335-2-29, in order to comply with safety regulations.

Note! It is not possible to perform an ISQ measurement during charging.

Accuracy

The instrument has an ISQ accuracy/resolution of ISQ +/- 1. When the SmartPeg is attached to an implant, the ISQ value can vary up to 2 ISQ depending on SmartPeg attachment torque.

Power, weight & size

Lithium-ion battery	3.7 VDC
Charging	Only use USB cable, type A-C, connected to a standard USB 2.0 or 3.0 (type A) port (Max 5.2 VDC).
Instrument size	206 x 36 x 25 mm
Package size	230 x 145 x 65 mm
Instrument weight	0.08 kg
Gross weight	0.40 kg

Environmental conditions during transport

Temperature	-40 ºC to +70 ºC
Relative humidity	10% to 95%
Pressure	500 hPa to 1060 hPa

Environmental conditions during use and storage

Temperature	+10 ºC till +35 ºC
Relative humidity	30% till 75%
Pressure	700 hPa till 1060 hPa
IP class	IP20

15) Troubleshooting

No measurement or unexpected value

Re-Used SmartPeg
The SmartPegs are disposable and should only be used for one or multiple measurement at one treatment session, for a single patient only. Repeated re-use may result in false readings due to wear and tear of the soft aluminium SmartPeg threads.

Wrong SmartPeg type selected for the implant
See SmartPeg reference list on **osstell.com/smartpegguide**.

Bone or soft tissue in between SmartPeg and implant
Make sure to clean the implant prosthetic connection before attaching the SmartPeg.

Electromagnetic interference
Remove the source of electromagnetic interference.

Instrument tip is held too far away from the SmartPeg
Normally it is sufficient to hold the instrument tip 2-4 mm away from the SmartPeg, but in some cases as close as 1 mm is necessary.

Instrument does not sense the SmartPeg, hence no measurement
Bring the instrument out of the mouth and then in the mouth again. Try to measure with approx. 45º angle towards the SmartPeg top as indicated in the display.

Instrument is not charging when USB cable is connected

Wrong USB cable used
Only use USB cable, type A-C, connected to a standard USB 2.0 or 3.0 (type A) port (Max 5.2 VDC).

Instrument does not start

Uncharged battery
Charge the instrument.

Instrument starts up with

Self-tests failed
Contact the local sales representative or distributor for further instructions.

Difficult to measure in an exact recommended direction

No space, e.g. due to adjacent teeth
Try to measure at a slightly different angle.

Difficulties attaching the SmartPeg

Wrong SmartPeg
Ensure that the SmartPeg is compatible with the implant system. See **osstell.com/smartpegguide**.

16) Service and support

In the event of an instrument malfunction contact the local sales representative or distributor for further instructions.

17) Waste and disposal

The instrument should be recycled as electrical equipment. SmartPegs should be recycled as metal. Whenever possible, the battery should be disposed in a discharged state to avoid heat generation through inadvertent short-circuiting.

Follow your local and country-specific laws, directives, standards and guidelines for disposal.

Li-ion

- Waste electrical equipment
- Accessories and spare parts
- Packaging