NeoTell™

Instructions for use
US only

neoss.com

Welcome

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

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 manufacturer.
- Unauthorized opening of the unit invalidates all claims under warranty and any other claims.

In addition to unauthorized disassembly, modification or repair of the unit and non-compliance with these instructions for use, improper use will void the warranty and release 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 website for recommended sleeves and section 13 for information on recommended cleaning.

⚠ Only use the recommended cleaning fluids listed in section 13 when cleaning the instrument. Other cleaning fluids may permanently damage the device 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 5, 8 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 SmartPegs not approved by SmartPeg 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

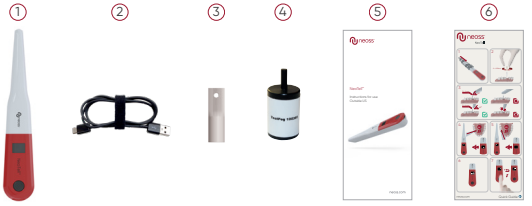
The instrument is a handheld instrument that involves the use of the non-invasive technique, Resonance Frequency Analysis. The system involves the use of a SmartPeg attached to the dental implant or abutment by means of an integrated screw. The SmartPeg is excited by a magnetic pulse from the instrument 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 100. 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 NeoTell 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
	Country and date of manufacture
SN	Serial number
	Do not dispose of with domestic waste. Li-ion battery
CE 0297	CE mark with identification number of the notified body
	Non-ionizing electromagnetic radiation
	Not sterilizable
	Temperature limitation
	Humidity limitation
	Atmospheric pressure limitation
IP20	Protected against solid foreign objects of 12.5 mm Ø and greater. No protection against water
	Use by date
LOT	Lot/batch code
STERILE R	Sterilized using irradiation
	For US market only: Prescription use only. US Federal Law restricts this device to sale by or on the order of a licensed practitioner
REF	Catalog number
	Do not reuse
MD	Medical device
	Data Matrix code for product information including UDI (Unique Device Identification)
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 ISQ.

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 website, presented in the front page of this manual.

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:

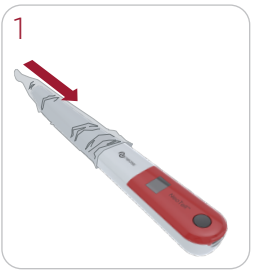
- Barrier sleeves are single patient use only.
- Discard used barrier sleeves in standard waste after each patient.
- Do not leave barrier sleeves on the instrument for extended periods.
- For recommended barrier sleeves visit website, presented in the front page of this manual.
- The instrument must be cleaned and sanitized with app-

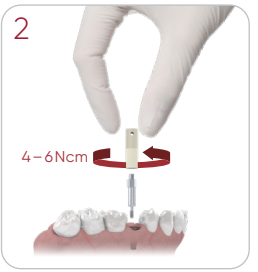
ropriate cleaning and disinfected with appropriate cleaning and disinfectant fluids after each patient. See section 13 Cleaning and Maintenance for acceptable agents.

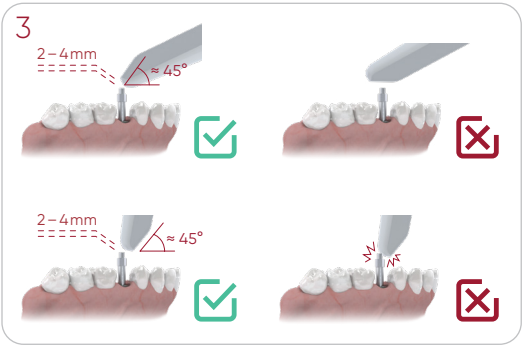
- A first measurement should be taken at implant placement to get a baseline for future measurements throughout the healing process. Before the final restoration, another measurement is taken which makes it possible to observe the stability development of the implant.
- It is recommended to measure in both Buccal-Lingual and Mesial-Distal direction to find the lowest stability. Therefore, the instrument prompts the user to measure in both these directions.

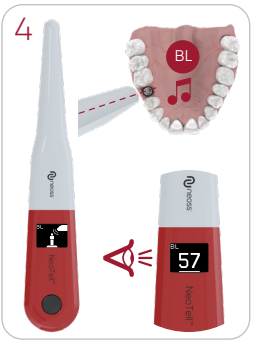
- We recommend you studying the more detailed information (quick guides) available on website, presented in the front page of this manual; to utilize the full functionality of your instrument.

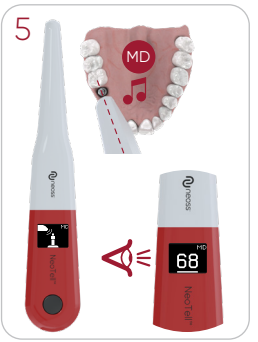
1. Activate the instrument by a short press on the button. The instrument will start-up and after showing the battery status, the instrument will be ready for measurement in the BL (Buccal–Lingual) direction, which is prompted in the display.
2. Place a barrier sleeve over the instrument. **See fig 1.**
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**. Attach the SmartPeg to the implant or abutment by screwing the SmartPeg Mount using finger force of approximately 4 – 6 Ncm. Do not over-tighten, 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**. Do not measure in the ways indicated with a red X mark in **fig 3**.
   - An audible sound indicates when a measurement has been made, and measured data will be shown in the display. **See fig 4**. 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**. **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**.
   The latest measurement will be presented for each direction, **see fig 6**.
   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**.
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.


1


2
4 – 6 Ncm

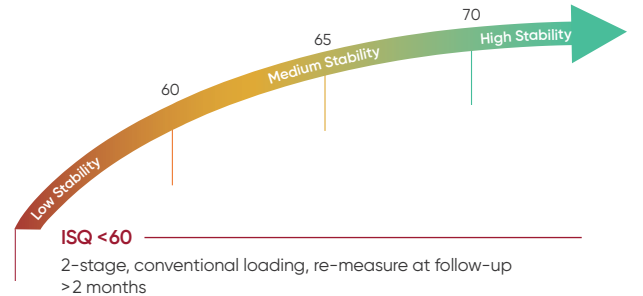

3
2 – 4 mm
≈ 45°
2 – 4 mm
≈ 45°


4
BL
57
NeoTell


5
MD
68
NeoTell


6
BL MD
57 68
NeoTell


7
NeoTell



ISQ <60

2-stage, conventional loading, re-measure at follow-up >2 months

Scientific references: 1, 6

Consider conservative approach due to low implant stability (i.e. relatively high implant mobility)

Scientific references: 7, 8

ISQ 60 – 64

Full splint: 1-stage, immediate loading

Partial case: 1-stage, early loading, re-measure at follow-up 6 – 8 weeks

Single case: 2-stage, conventional loading, re-measure at follow-up >2 months

Scientific references: 1, 5, 6

ISQ 65 – 69

Full splint: 1-stage, immediate loading

Partial case: 1-stage, immediate loading

Single case: 1-stage, early loading, re-measure at follow-up 6 – 8 weeks

Scientific references: 1, 3, 4

ISQ ≥70

Full splint: 1-stage, immediate loading

Partial case: 1-stage, immediate loading

Single case: 1-stage, immediate loading

Scientific references: 1, 2, 3, 9

Scientific references

1. Sennerby L. Implantologie 2013;21(1):21-33
2. Kokovic V, Jung R, Feloutzis A, Todorovic V, Jurisic M, 2. Hämmerle C. Clinical Oral Implants Research, 00, 2013, 1-6
3. Bornstein M, Hart C, Halbritter S, Morton D, Buser D. Clin Implant Dent Relat Res 2009
4. Serge Baltayan, Joan Pi-Anfruns, Tara Aghaloo, Peter Moy J Oral Maxillofac Surg 74:1145-1152, 2016
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6. Rodrigo D, Aracil L, Martin C, Sanz M. Clin. Oral Impl. Res. 21, 2010; 255-261
7. Pagliani L, Sennerby L, Petersson A, Verrocchi D, Volpe S & Andersson P. Journal of Oral Rehabilitation 2012
8. Trisi P, Carlesi T, Colagiovanni M, Perfetti G. Journal of Osteology and Biomaterials, Volume 1, Number 3, 2010
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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, see website, presented in the front page of this manual.

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

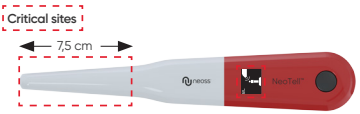
Assuming there is access to the implant, ISQ measurements should be performed at implant placement and before the implant is loaded or the abutment is connected. After each measurement, the ISQ values are used as the baseline for the next measurement performed. A change in the ISQ value reflects a change 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.

13 – Cleaning and Maintenance

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

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, wipe down the housing of the device for at least one (1) minute.
3	Visually inspect 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 section 13. 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.

SmartPegs:	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 auto-clave 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

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

NeoTell 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:

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, presented in the front page of this manual.

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. 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 +/– 1 ISQ. 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:	206×36×25 mm
Package size:	272×140×75 mm
Instrument weight:	0,08 kg
Gross weight:	0,82 kg

Environmental conditions during transport:

Temperature:	-40° C to +70° C
Relative humidity:	10% to 95%
Pressure:	500 hPa to 1060 hPa

Environmental conditions during use and storage:

Temperature:	+10° C to +35° C
Relative humidity:	30% to 75%
Pressure:	700 hPa to 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 the website presented in the front page of this manual.
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.

Unit 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 direction.

Difficulties attaching the SmartPeg :

Wrong SmartPeg
Ensure that the SmartPeg is compatible with the implant system. See website, presented in the front page of this manual.

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.

- Waste electrical equipment
- Accessories and spare parts
- Packaging

OUR OFFICES

ARC SOLUTIONS
Arc Solutions
Box 13011
SE-250 13 Helsingborg
Sweden
T: +46 42 301 74 40
E: info@arcsolutions.se

AUSTRALIA & NEW ZEALAND
Neoss Australia Pty. Ltd
G04 Ground Floor North Tower
John Oxley Centre
339 Coronation Drive
Milton Qld 4064
Australia
Phone: +61 7 3216 0165
E: info.au@neoss.com

CHINA
Neoss China
7F, #303, Songhu Rd. (KIC Build #11)
Yangpu District
Shanghai, 200433
PR China
T: +86 21 80143135
E: china@neoss.com

EUROPEAN DISTRIBUTION
Neoss AG
The Circle 23
8058 Zurich-Airport
Switzerland
E: distributors@neoss.com

GERMANY & AUSTRIA
Neoss GmbH
Im Mediapark 5b
50670 Köln
T: +49 221 96980 10
F: +49 221 96980 199
E: info@neoss.de

ITALY
Neoss Italia S.r.l.
Viale Certosa 138
IT-20156 Milano
T: +39 02 92952 1
E: italia@neoss.info

MIDDLE EAST & AFRICA
Neoss Limited (DMCC BRANCH)
Unit 1505 Fortune Tower
Cluster C – JLT
Dubai
P.O. Box 64093
United Arab Emirates
E: info.mea@neoss.com

SWEDEN, DENMARK & NORWAY
Neoss Norden AB
Arvid Wallgrens backe 20
SE-413 46 Göteborg
T: +46 31 88 12 80
E: info@neoss.se

UNITED KINGDOM & REPUBLIC OF IRELAND
Neoss Ltd
Windsor House
Cornwall Road
Harrogate
HG1 2PW
T: +44 1423 817 733
F: +44 1423 817 744
E: info@neoss.com

UNITED STATES
Neoss Inc.
890 Winter Street, Suite 120
Waltham, MA 02451
T: +1 866 626 3677
F: +1 818 432 2640
E: marketingusa@neoss.com

Contact your local representative for product availability details.
All products are not available in every market.

Distributed by:
Neoss Group, Windsor House, Cornwall Road, Harrogate, HG1 2PW
Phone: +44 1423 817-733 | Email: info@neoss.com

Manufacturer:
Osstell AB, Stampgatan 14, 411 01 Göteborg, Sweden

NeoTell Instructions for Use
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