

Altus™ Gingiva height measuring tool Instructions for Use



Altus™ Gingiva height measuring tool
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1 INTRODUCTION

Please read this instruction manual before you use the Altus™ gingiva height measuring tool for the first time.

Correct adherence to the instructions below is the prerequisite for the proper operational reliability of the system.

The manufacturer accepts no liability whatsoever for any damage caused by failure to observe these instructions.

2 PRODUCT DESCRIPTION

The Altus™ gingiva height measuring tool allows the precise measurement of the gingiva height above the implant for accurate determination and choice of the abutment height.




The Altus™ gingiva height measuring tool consists of a slider (PEEK) and a multifunctional scale part (Stainless Steel)

The positioning onto the implant is done by placing the scale part onto the implant shoulder. The specially designed gingiva plate locates the highest gingiva position in all situations around the implant.

A thread can be fixed to the hole in the gingiva plate, which serves as a safeguard against aspiration.

The Altus™ gingiva height measuring tool has a guide for tweezers for accessing even the most difficult positions in the mouth.

2.1 Altus™ components

Image	Art. No.	Description	Specifications	Quantity per unit
	2013.901	Altus™ gingiva height measuring tool (sterilizable)	Slider: PEEK Scale part: Stainless Steel	1 piece
	3.03.180 	Altus™ gingiva height measuring tool for Thommen Medical (sterilizable)	Slider: PEEK Scale part: Stainless Steel	1 piece

2.2 Indications

Altus™ is intended to be used on implant platforms with a hole diameter of the inner connection measuring up to 4.5 mm.

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2.3 Contraindications

- The Altus™ gingiva height measuring tool is not applicable on gingiva heights greater than 6 mm over the implant.
- Not suitable for implants with an external connection except Thommen Medical implant connection.
- Not to be used for implant platforms with a hole diameter of the inner connection greater than 4.5 mm.

3 WARNINGS

- Allergies and sensitivities in connection with the materials cannot be ruled out. The product must not be used for patients with suspicion/knowledge of existing allergies to one or more materials used. Improper cleaning using toothbrushes and toothpaste to clean the product mechanically can lead to premature wear in functional areas.
- The product has to be inspected prior to use. The packaging must be sealed without any visible damage. The content must be checked for any visible damage. The product integrity cannot be guaranteed if the outer protective packaging is damaged. The contents of an opened or damaged packaging may no longer be used.

4 CLEANING AND STERILIZATION

Altus™ gingiva height measuring tool is provided non-sterile. All Altus™ components have to be cleaned and sterilized prior to intra-oral use. All surfaces have to be accessible for cleaning and sterilization. This requires prior removal of Altus™ for the preparation (cleaning and sterilization).

Disassemble Altus™ before the cleaning/sterilization process as shown in Fig.1



Fig.1

Cleaning: Clean by rinsing under flowing water.

Sterilization: Unless directed otherwise, steam sterilization is recommended. Seal the product in suitable autoclave foil. Steam sterilization with fractionated vacuum procedure with at least 3 vacuum steps (with adequate product drying time: at least 20 minutes) with maximum sterilization temperature of 138 °C (280 °F; plus tolerance) in compliance with EN ISO 17665.

Sterilization time, exposure time at sterilization temperature, of at least 4 minutes at 132 °C (270 °F) for fractionated vacuum steps or 18 minutes at 134 °C (273 °F).

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Notes:

- *Do not store sterilized product for later use.*
- *The user should ensure that the appropriate sterilizer with above defined parameter is used for sterilization.*

The manufacturer does not accept any liability for regular maintenance and monitoring of cleaning, disinfection and sterilization equipment. This responsibility rests with the operator.

5 CAUTION/PRECAUTIONS

- The Altus™ gingiva height measuring tool should not be immersed into physiological saline solution, as prolonged contact could lead to corrosion and surface changes.
- Neither metal brushes nor abrasive agents must be used to clean Altus™.
- Extra care has to be taken specifically prior to sterilization to ensure that no residue is left inside hollow spaces of the Altus™ gingiva height measuring tool.
- Slight changes of the colour of the handle cannot be ruled out after cleaning. These do not affect the function of the measuring tool.
- Altus™ components must not come into contact with agents containing chloride or fluoride.

Improper handling can result in corrosion, oxidation, excessive wear or functional impairment of Altus™ and may not be used anymore in these cases.

During intraoral use, make sure that Altus™ is properly fixed by a thread through the hole in the gingiva plate to prevent aspiration.

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6 PROCEDURE/APPLICATION

6.1 Preparation

6.1.1 Determine the matching end of the scale part (Art. No. 2013.901)



Implant	Diameter
Astra Tech OsseoSpeed®	4.5mm, 5.0mm
BEGO Semados® RX/R SX	4.1mm, 4.5mm
Biomet 3i Certain®	5.0mm
Camlog® /Conelog®	5.0mm
Dental-Ratio OKTAGON® Tissue Level	RP 3.3mm, 4.1mm, 4.8mm
Nobel Active®	RP 4.3mm, 5.0mm
Nobel Biocare Replace Select®	5.0mm, 6.0mm
Straumann SynOcta®	RN 4.8mm, WN 6.5mm
Zimmer Tapered Screw Vent/MIS SEVEN/Bio Horizons Internal	4.5mm (platform)

Astra Tech OsseoSpeed®	3.5mm, 4.0mm
BEGO Semados® RX/R SX	3.75
Biomet 3i Certain®	3.4mm, 4.1mm
Bredent® SKY	3.5mm - 5.5mm
Camlog® /Conelog®	3.3mm, 3.8mm, 4.3mm
Dental-Ratio OKTAGON® Bone Level	BL 3.3mm, 4.1mm,
Dentsply Friudent Ankylos®	3.4mm, 3.8mm, 4.5mm, 5.5mm
Medentika M-Implant®	3.0mm - 5.0mm
Nobel Active®	NP 3.5mm
Nobel Biocare Replace Select®	3.5mm, 4.3mm
Straumann Bone Level®	NC, RC
Zimmer Tapered Screw Vent/MIS SEVEN/Bio Horizons Internal	3.5mm (platform)

Two different ends of the scale part are available since implant diameters and hole diameters of the inner connection can vary. In case of doubt, check if Altus™ fits properly on a laboratory analogue to ensure a proper fit on the implant shoulder.

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6.1.2 Determine the matching end of the scale part (Art. No. 3.03.180)

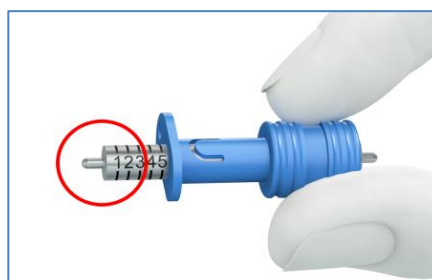
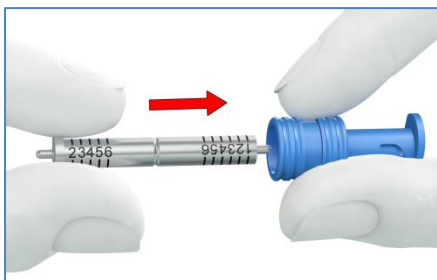


Implant Thommen Medical	Diameter
SPI® ELEMENT Implant RC INICELL®	PF 4.5mm, 5.0mm, 6.0mm
SPI® ELEMENT Implant MC INICELL®	PF 4.5mm, 5.0mm, 6.0mm
SPI® ELEMENT Implant LC INICELL®	PF 4.5mm, 5.0mm, 6.0mm
SPI® CONTACT Implant RC INICELL®	PF 4.5mm, 5.0mm, 6.0mm
SPI® CONTACT Implant MC INICELL®	PF 4.5mm, 5.0mm, 6.0mm
SPI® ELEMENT Implant	PF 4.5mm, 5.0mm, 6.0mm
SPI® CONTACT Implant	PF 4.5mm, 5.0mm, 6.0mm

SPI® ELEMENT Implant RC INICELL®	PF 3.5mm, 4.0mm
SPI® ELEMENT Implant MC INICELL®	PF 3.5mm, 4.0mm
SPI® ELEMENT Implant LC INICELL®	PF 3.5mm, 4.0mm
SPI® CONTACT Implant RC INICELL®	PF 3.5mm, 4.0mm
SPI® CONTACT Implant MC INICELL®	PF 3.5mm, 4.0mm
SPI® ELEMENT Implant	PF 3.5mm, 4.0mm
SPI® CONTACT Implant	PF 3.5mm, 4.0mm

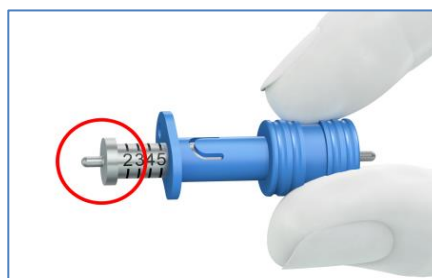
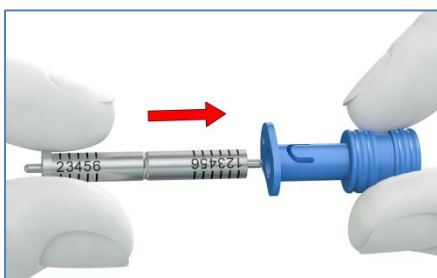
6.1.3 Assembly of the Altus™ gingiva height measuring tool

Variant 3.3 mm scale part (Art. No. 3.03.180 / 2013.901)



Push the scale part into the slider until it clicks. Ready with 3.3 mm scale part.

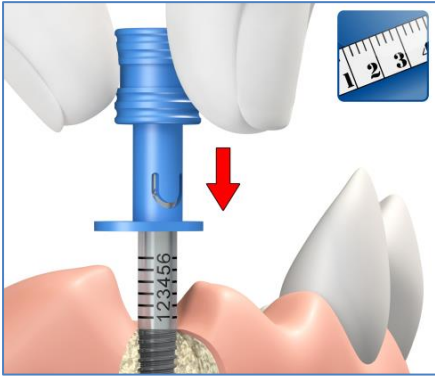
Variant 4.3 / 4.5 mm scale part (Art. No. 3.03.180 / 2013.901)



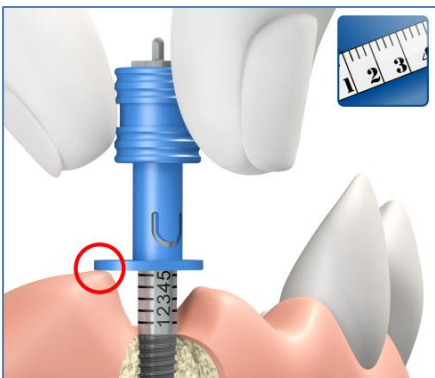
Push the scale part into the slider until it clicks. Ready with 4.3/4.5 mm scale part.

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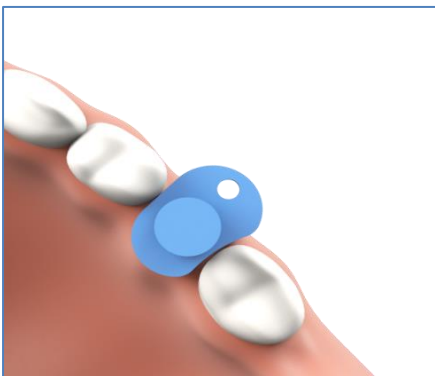
6.2 Measuring procedure



Place Altus™ on implant shoulder.

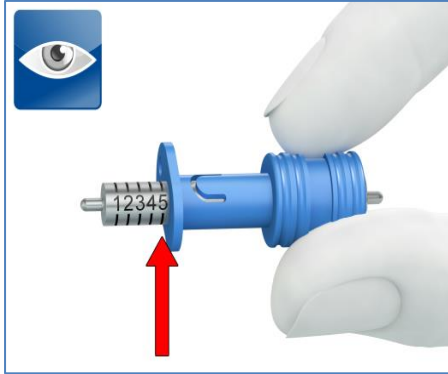


Push the slider downwards until the highest point of the gingiva has been located by the measuring plate.



The specially designed gingiva plate lets you measure the highest point of the gingiva in all situations around the implant.

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Remove Altus™ carefully from the oral cavity and read the measurement result from the scale part.

7 STORAGE

The product must be stored in a dry place in the original packaging at room temperature and not exposed to direct sunlight. Incorrect storage may influence the characteristics of the product.

8 VALIDITY

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9 SIGNS AND SYMBOLS



Valoc products with the CE mark fulfil the requirements of the Medical Devices Directive 93/42 EEC



Article number



Do not reuse



Batch code



Manufacturer



Do not expose to sunlight



Non-sterile



Caution: U.S. Federal law restricts this device to sale by or on the order of a dental professional



Instructions for use

Products indicated with ® are registered brand names of the manufacturers.

Notice: The product may be subjected to further development. In this connection we reserve the right to make product changes in relation to the design and composition.