Instructions for Use

The Docklocs Attachment System includes: Docklocs Abutments, Denture Attachment Housings, Retention Inserts, Ancillary Processing Components (including: block-out spacer, laboratory analog, processing spacer, impression coping with black processing insert), Try-in Abutments and Tooling (including: Retention Insert Tool and abutment drivers for torque wrenches and latch handpieces).

This document contains the most current Instructions for Use. Please read and retain.

DESCRIPTION

The Docklocs Attachment System is a universal hinge, resilient attachment for endosseous implants and angled or straight multi-unit abutments in the mandible or maxilla that is designed to restore masticatory function. The attachment system is patient removable and therefore allows for the prosthesis to be removed and replaced by the patient.

INDICATIONS FOR USE

The Docklocs Attachment System is designed for use with full arch overdentures or partial dentures retained in whole or in part by endosseous implants in the mandible or maxilla.

CONTRAINDICATIONS

Not recommended for use with a single implant with greater than 20 degrees vertical divergence or if the divergence between the implant axes is more than 40 degrees. Not appropriate where a totally rigid connection is required.

CAUTION

Federal law in the USA and most other countries restricts this device to sale only by or on the order of a licensed dentist.

NOTICE TO USERS IN THE EUROPEAN UNION

Any serious incident that has occurred in relation to the device(s) in which this Instructions for Use applies should be reported to the manufacturer identified in this Instructions for Use and the competent authority of the Member State in which the user and/or patient is established.

STORAGE AND HANDLING

The Docklocs Attachment System in its original, undamaged packaging is not subject to any special considerations for transport, storage and handling.

WARNINGS AND PRECAUTIONS

Product should be inspected for integrity prior to use. Product from damaged packaging should not be used on patients. In the event that the packaging is damaged, the damaged packaging with the product should be returned to the manufacturer and a replacement will be provided only if damage to packaging is caused by product shipment.

If the Docklocs Implant Abutment is subjected to inappropriate loading conditions, there may be a potential risk of metal fatigue.

As surgical instruments are susceptible to damage and wear, they should be inspected before each use. Markings should be visible and legible. Any reusable instrument should be replaced if damage or wear is present to ensure proper functionality. The number of uses will vary and depends on a variety of factors including but not limited to bone density encountered, handling, proper cleaning, autoclave exposure, and storage conditions (do not store tools or instruments wet). Over time, repeat sterilization may affect appearance and visibility of markings. When applicable to the surgical instrument, check the connection feature for wear to ensure the connection is not damaged.

Patient evaluation including the determination of the general health, oral hygiene habits and status, motivation towards good dental care, and anatomical acceptability prior to the placement of the implant attachments as part of restorative process, is critical. Thorough evaluation of the patient's medical status and health history is mandatory. Treatment planning is vital to the success of the implant and prosthesis.

Always follow the instructions for use from the implant manufacturer! There are implant manufacturers who only allow a divergence of 10° per implant to avoid excessive mechanical stress.

The use of this attachment system requires that the clinician be thoroughly familiar with the product and the method for its use and application. The clinician must also use reasonable judgment in deciding when and where to use the product.

SINGLE-USE DEVICES

The Docklocs Attachment System components, with the exception of tools and instruments, are single-use devices and are provided non-sterile. Single-use devices must not be reused or re-sterilized. Reuse of a single-use device may cause harm to the patient in the transfer of blood, tissue or saliva that may contain infectious disease. Single-use devices may not function as intended if re-sterilized and may result in an improper surgical procedure and lead to improper function or failure of the device.

Docklocs Retention Inserts: The inadvertent re-use of Docklocs nylon Retention Inserts could cause loss of retention of the overdenture due to wear from previous use or damage during removal with the Docklocs Retention Insert Tool.

Docklocs Attachments: The inadvertent re-use of Docklocs Attachments could contain patient contamination, build-up and cause the subsequent wear of the Retention Inserts. This would result in improper fit and function which cause the loss of retention of the prosthesis.

MULTI-USE DEVICES

The surgical instruments and tools of the Docklocs Attachment System are multi-use devices. Reusable tools and instruments must be cleaned and sterilized prior to reuse on patients.

Tooling: The Docklocs Tools are designed for multiple uses and are provided NON-STERILE.
Follow the instructions provided below for proper sterilization of non-sterile components and the instructions for cleaning and resterilization of reusable components.

CLEANING AND STERILIZATION

The Docklocs Attachment System and other restorative components, instruments, replacement Docklocs Attachments (sold separately), and tools are supplied NON-STERILE and should be sterilized prior to use on patients.

The following sterilization procedures should be carried out prior to use:

Docklocs® Abutment, Abutment Screws and Instruments

Method	Procedure	Temperature	Minimum holding time *	Drying period
Superheated steam	Vacuum Process (3x fractionated pre-vacuum)	134°C	4 minutes	20 minutes

* Indicated are the minimum holding times. The operating times are longer and may vary on the instrument side.

PLEASE READ THE MANUFACTURER'S INFORMATION AND INSTRUCTIONS FOR CLEANING/STERILIZING MEDEALIS SURGICAL INSTRUMENTS AND PROSTHETIC COMPONENTS at

https://www.medealis.de/service/downloads

Docklocs Retention Inserts, Processing Inserts, Block-out Spacers, Parallelization Posts, Denture Attachment Housings with Processing Inserts and Impression Copings with Processing Inserts may only be chemically sterilized.

Note: A liquid chemical sterilant approved by the FDA or other applicable regulatory entity for critical devices that are heat-sensitive and incompatible with sterilization methods such as steam and gas/vapor/plasma low temperature processes may be used following the manufacturer's directions for the sterilization of the device.

DISPOSAL

Dispose of used devices which pose a risk of infection according to facility clinical waste procedures and applicable local and state regulations.

Recommended tightening torque for Straight Abutments and Retaining Screws for Angled Abutments

Using a calibrated torque wrench, tighten the Docklocs Abutment or the Abutment Screw to the recommended torque in the chart below:

Implant System	Docklocs Abutment (in Ncm)	Abutment Screw for Angled Abutments (in Ncm)
Straumann® Bone Level NC®	30	30
Straumann® Bone Level RC®	30	30
Straumann® Tissue Level RN®	30	30
Straumann® Tissue Level WN®	30	30
Straumann® Narrow Neck CrossFit®	30	30
Camlog® iSy	25	25
Camlog® Ø3.3mm	20	20
Camlog® Ø3.8mm	30	30
Camlog® Ø4.3mm	30	30
Camlog® Ø5.0mm	30	30
Conelog® Ø3.3mm	20	20
Conelog® Ø3.8mm	30	30
Conelog® Ø4.3mm	30	30
Conelog® Ø5.0mm	30	30
MEGAGEN AnyRidge®	**30**	**30**
MEGAGEN AnyOne Onestage®	**30**	**30**
MEGAGEN AnyOne Internal®	**30**	**30**
MEGAGEN AnyOne mini®	**30**	**30**
Botticelli small	25	25
Botticelli regular	25	25
Bego® Semados® S / RI / RS / RSX 3,75–4,1	30	30
Bego® Semados® S / RI / RS / RSX 4,5	30	30

Implant System	Docklocs Abutment (in Ncm)	Abutment Screw for Angled Abutments (in Ncm)
Medentis® ICX	30	30
ASTRA TECH® 3,5-4,0mm	25	25
ASTRA TECH® 4,5-5,0mm	30	30
ASTRA TECH® EV 3,6mm	25	25
ASTRA TECH® EV 4,2mm	30	30
ASTRA TECH® EV 4,8mm	30	30
Ankylos® C/X	25	/
Nobel Biocare® Internal tri-channel connection NP (3,5)	35	35
Nobel Biocare® Internal tri-channel connection RP (4,3)	35	35
Nobel Biocare® Internal tri-channel connection WP (5,0)	35	35
Nobel Biocare® NobelActive™Conical NP	35	35
Nobel Biocare® NobelActive™Conical RP	35	35
Nobel Bocare® Branemark System® External hex connection NP	35	35
Nobel Bocare® Branemark System® External hex connection RP	35	35
Nobel Bocare® Branemark System® External hex connection WP	35	35
Zimmer Biomet® Tapered Screw-Vent® 3.5	30	30
Zimmer Biomet® Tapered Screw-Vent® 4.5	30	30
Zimmer Biomet® Tapered Screw-Vent® 5.7	30	30
Zimmer Biomet® 3i External Hex NP 3.25/3.4	30	30
Zimmer Biomet® 3i External Hex 4,1	30	30
Zimmer Biomet® 3i 3.4 Certain® Con.	30	30
Zimmer Biomet® 3i 4.1 Certain® Con.	30	30
BioHorizons® Internal Hex 3.5mm	30	30
BioHorizons® Internal Hex 4.5mm	30	30
BioHorizons® Internal Hex 5.7mm	30	30

Products labeled with ® are registered trademarks of the respective manufacturer.

Important! The Recommended Torque Value must be verified after 5 minutes and adjusted if required.

PROSTHETIC PROCEDURES

Based on the results of the patient's pre-surgical assessment, the clinician should select and order the appropriate Docklocs Abutment based on the type of implant, diameter and tissue height.

It is imperative that all bone and soft tissue be removed from the superior aspect of the implant body to guarantee complete seating of the Abutment.

Impression and Stone Model Fabrication

- With the Docklocs Abutments torqued in place, snap the Impression Copings on the Abutments until they are seated firmly.
- Proceed with taking an impression.
- Remove the tray and snap an Analog into each Impression Coping.
- Capture the abutment position in stone using standard methods for fabricating a laboratory stone model.

Prosthesis Fabrication

- Seat the Docklocs Denture Attachment Housings with the black Processing Inserts on each of the abutments.
- Fabricate the prosthesis using standard laboratory techniques.
- When delivering the prosthesis, use the lowest level Retention Insert to begin with and increase the retention level if needed.

Chair-Side Denture Attachment Housing Pick-Up Technique (Optional)

- Place a Block-Out Spacer around each abutment and press down.
- Seat the Docklocs Denture Attachment Housings with the black Processing Inserts in place on each of the Abutments.
- Secure the Denture Attachment Housings to the prosthesis using light-cure, auto-polymerizing or composite resin, following the respective material guidelines for each pick-up technique.

Prosthesis Delivery

- Once the fit of the prosthesis is verified, remove the black Processing Inserts from each Denture Attachment Housing using the Retention Insert Tool (refer to the Retention Insert Tool IFU for additional instruction).
- Replace them with the lowest level Retention Insert to begin with and increase the retention level if needed. Firmly snap the prosthesis in place, ensuring that each insert is fully engaged onto each abutment.

HEALING PHASE

For delayed loading protocols: Relieve the denture to ensure the abutments are not in contact with any denture acrylic. A soft liner may be added to the denture to ensure patient comfort during the healing phase.

PATIENT CARE

Good oral hygiene is vital to success with the Docklocs Attachment System. The patient should be made aware of the following:

- Docklocs Attachments must be thoroughly cleaned each day to prevent buildup of plaque biofilm. The patient should use a soft nylon bristle or end-tufted toothbrush with a non-abrasive toothpaste to clean the Abutments.
- The coarse particles in abrasive toothpastes may scratch the surfaces of the Abutments and cause additional plaque accumulation.
- An irrigation system is recommended to flush out debris from the inside of the Docklocs Retention Inserts.
- Docklocs Retention Inserts are made of a soft plastic material (nylon) to allow the overdentures to be removed and replaced regularly. Plastic materials are subject to wear as part of normal use and may require replacement.
- Bruxism wears the Docklocs attachments and may reduce the longevity of Retention Inserts.

Patients should be instructed to maintain routine follow-up visits for hygiene and evaluation of attachment function. Should a patient experience any discomfort or loss of overdenture retention, they should consult a dental professional.

Follow-up visits are recommended at 6-month intervals. Abutments must be re-tightened at follow-up visits to the torque specifications outlined above. Failure to re-tighten Abutments could lead to screw loosening and Abutment fracture. Patients should be examined for signs of inflammation around the implant abutments and for implant mobility during every follow-up visit.

Inserting and Removing Overdentures

The patient should be instructed on how to properly insert the Overdenture. The patient should make sure they can feel that it is positioned over the Abutments prior to applying pressure. The patient should use both hands and press down on each side and firmly snap the Overdenture into place.

NOTE: The patient must NOT bite their Overdentures into place, as this force will result in improper wear of the Abutments and Retention Inserts. The Overdenture is to be removed by the patient by placing their thumbs under the edges of the Overdenture flanges and pulling each side upward (mandibular denture) or downward (maxillary

denture) simultaneously. Use of the tongue may aid in removal. Once removed, through cleaning is recommended.

Cleaning of Implant-Retained Overdentures

Instruct the patient to follow the protocol below to ensure the longevity of their Overdenture.

1. Fill a washing basin with warm water to prevent fracture of the Overdenture. Apply non-abrasive toothpaste onto a soft nylon bristle or end-tufted toothbrush and thoroughly clean every surface of the Overdenture.
2. Remove the Overdenture every night and rinse with plain water.

Further Information

Traditional restorative protocols should be followed to process the attachments into the patient's Overdenture. Standard Overdenture care and maintenance should be followed in order to ensure the longevity of each restoration.

Further information can be found in our Technical Manual which is available in our Download Section.

https://www.medealis.de/service/downloads

EXPLANATION OF OUTER PACKAGING LABEL SYMBOLS

Symbol	Title	Explanatory Text	Standard	Reference
	Manufacturer	Indicates the medical device manufacturer, as defined in EU Directive 93/42/EEC	EN ISO 15223-1	5.1.1
	Authorized Representative in the European Community	Indicates the authorized representative in the European Community	EN ISO 15223-1	5.1.2
	Catalogue Number	Indicates the manufacturer's catalogue number so that the medical device can be identified	EN ISO 15223-1	5.1.6
	Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified	EN ISO 15223-1	5.1.5
	Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure	EN ISO 15223-1	5.4.2
	Consult Instructions for Use	Indicates the need for the user to consult the instructions for use	EN ISO 15223-1	5.4.3
 XXXXX	Consult Electronic Instructions for Use	"Consult instructions for use" for an electronic instruction for use (eIFU). The eIFU indicator can be a manufacturer's website URL or some other appropriate indication that the instructions for use are available in an electronic format.	EN ISO 15223-1	5.4.3 / Annex A.15
	Do Not Resterilize	Indicates a medical device that is not to be resterilized	EN ISO 15223-1	5.2.6
	Non-Sterile	Indicates a medical device that has not been subjected to a sterilization process	EN ISO 15223-1	5.2.7
 YYYY-MM-DD	Use-by Date	Indicates the date after which the medical device is not to be used	EN ISO 15223-1	5.1.4
	Date of Manufacture	Indicates the date when the medical device was manufactured	EN ISO 15223-1	5.1.3
	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened	EN ISO 15223-1	5.2.8
 XXXX	European Mark of Conformity	Indicates device is in conformance with Medical Device Directive 93/42/EEC	MDD 93/42/EEC	MDD 93/42/EEC Annex XII
	European Mark of Conformity	Indicates device is in conformance with Medical Device Regulation EU 2017/745	MDR EU 2017/745	MDR EU 2017/745 Annex V
Rx only	Rx only	Federal law restricts this device to sale by or on the order of a dentist only	US CFR Title 21	801.15(c)(1)(i)(F)
	Quantity	Indicates the number of items within the package	N/A	N/A
	Unique Device Identifier	Indicates the Unique Device Identifier Information	DIS 15223-1 (2019)	5.7.10
	Medical Device	Indicates the item is a medical device	DIS 15223-1 (2019)	5.7.7
	Keep Dry	Indicates a medical device that must be protected from moisture	EN ISO 15223-1	5.3.2
	Protect from exposure to light	Indicates a medical device that requires protection from light sources	EN ISO 15223-1	5.3.4

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