Summary of Safety and Clinical Performance (SSCP)

According to MDCG 2019-9

In accordance with the Medical Device Regulation MDR (EU) 2017/745

From:
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Summary

Introduction

This Summary of Safety and Clinical Performance (SSCP) has been prepared to provide a clear and understandable overview of the key safety, efficacy and performance aspects of the product.

The aim is to inform healthcare professionals, users and the public about relevant clinical data and safety information to ensure a solid decision-making basis for the safe use of the product.

The SSCP does not replace the Instructions for Use (IFU), which is the central document for ensuring the safe use of the Docklocs Attachment System, nor does it contain diagnostic or therapeutic recommendations for users or patients.

1. The labelling of the product and the manufacturer

The Docklocs Attachment System for denture fixation is designed for the attachment of complete dentures (overdentures) or partial dentures that are fully or partially supported by endosseous implants in the mandible or maxilla. The Docklocs Attachment System allows the patient to remove and reinsert their denture.

1.1. Trade name(s) of the product

Trade name	Sales partner/implant manufacturer	Article number identifier	Country
Docklocs			Europe
LOcON	NT-Trading GmbH & Co KG		Europe
Clic'n Loc	LGD Dental	CL	France
PrimeLOC	Dyna Dental, LASAK Ltd.	.P	Europe
K-Lock	Klockner, Soadco, Archimedes		Spain
Overlock	ANCLADÉN, SL	.OL	Spain
Direktlocs	Dental Direct GmbH		Europe

The products are differentiated by adding an abbreviation to the existing article number or by adding an additional product number of the sales partner which appears as the REF number on the label.

1.2. Name and address of the manufacturer

MEDEALIS GmbH
Im Steinböhl 9
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Germany

www.medealis.de
E-mail: office@medealis.de
Tel: +49(0)6207 2032 597

Responsible person: Klaus Krüger

1.3. SRN of the manufacturer

DE-MF-000019555

1.4. Basic UDI-DI

Basic UDI-DI have been assigned for the products of the Docklocs Attachment System. These are listed under 3.1 Overview of the system components.

1.5. Description

The Docklocs abutments of the Docklocs attachment system are implantable products.

Docklocs secondary parts
Docklocs abutments are prefabricated dental abutments that are used in combination with endosseous implants as the basis for anchoring the prostheses in the upper or lower jaw. They are available in various designs and gingival heights.

1.5.1 Medical device nomenclature

EMDN	UMDNS	GMDN	MDN
P01020101	17-113	44879	1103

1.6. Risk class of the medical device

Class 2b Rule 8

1.7. Year of first certificate (CE) for the product

The first CE certificate for the product was issued by mdc medical device certification GmbH in 2018.

1.8. Authorised representative; name and SRN

There is no authorised representative.

1.9. Name of the Notified Body

mdc medical device certification GmbH
Kriegerstraße 6 / 70191 Stuttgart

Identification number: 0483

2. Intended use of the device

2.1. Intended use

The Docklocs Attachment System is designed to attach removable full or partial dentures completely or partially to abutments held by dental implants in mandible or maxilla.

2.2 Indication(s) and target group(s)

INDICATIONS

- The Docklocs abutments are intended for connection to endosseous dental implants in mandible or maxilla.
- The Docklocs cap is designed as an additional retaining element on individually milled dental bars.
- The female part system is used to attach the prosthesis to the abutments via a detachable snap connection.
- The screwdrivers are intended for tightening or loosening the secondary parts and retaining screws.
- The auxiliary instruments and accessories are intended for the planning and fabrication of the prosthetic restoration.

INTENDED USER AND PATIENT GROUP

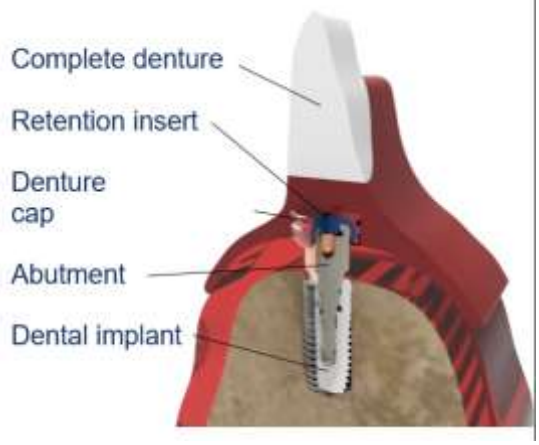
- The Attachment System is to be used exclusively by dental professionals!
- The Attachment System is intended for patients undergoing treatment with dental implants.

2.3 Contraindications and/or restrictions

CONTRAINDICATIONS

- Use with a single implant is not recommended if the vertical divergence is over 20 degrees.
- Use is not recommended, if the divergence between the implant axes is over 40 degrees.
- Use is not suitable, if complete fixation of the denture is desired.
- The attachment system is not suitable for patients who suffer from hypersensitivity or allergy to titanium (Ti-6Al-4V), zirconium carbonitride (ZrCN) or polyamide PA (material of the retention inserts).

3. Description of the product



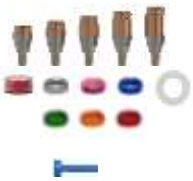
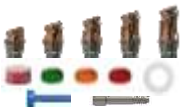
The Docklocs Attachment System is a system for the elastic fixation of removable partial or full dentures on osseointegrated dental implants. Depending on straight or angled abutments are used.
The abutments (secondary parts) are made of titanium and have a hard layer of zirconium carbonitride. These abutments are available in different abutment heights to suit every gingival height.
The denture cap is a titanium cap that holds a plastic retention insert. The denture cap is polymerised into the denture. The prosthesis is held in place by the retention insert, which snaps onto the head of the abutment. This ensures a secure hold between the prosthesis/abutment and implant/jaw. The retention inserts are interchangeable and available in different colour-coded retention force levels.

3.1. Overview of the system components

3.1.1 Abutments

Docklocs abutments are prefabricated dental abutments that are used in combination with endosseous implants as basis for anchoring the prostheses in mandible or maxilla. They are available in various designs and gingival heights. The abutments are suitable for many implant systems.

Secondary parts			
Products	**Picture**	**Material**	**Number Basic UDI-DI**
Straight abutment one-piece		Titanium Grade 5(1) Ti-6AL-4V according to ASTM F136 and ISO 5832-3 and zirconium carbonitride (ZrCN)(2) coating	++EMESA001YM
Angled abutment 18° with retaining screw		Titanium Grade 5(1) Ti-6AL-4V according to ASTM F136 and ISO 5832-3 and zirconium carbonitride (ZrCN)(2) coating	++EMESA002YP
Cap/bar abutment		Titanium alloy(1) and zirconium carbonitride(2) coating	++EMESA001YM
Retaining screw		Titanium Grade 5(1) Ti-6AL-4V according to ASTM F136 and ISO 5832-3	++EMESA004YT

Treatment unit secondary parts			
Products	**Picture**	**Material**	**Number Basic UDI-DI**
Abutment Set A Abutment one-piece straight with denture cap and black processing insert, retention insert blue/pink/clear/red/orange/green, block-out spacer and parallel post		Titanium alloy(1) with zirconium carbonitride (ZrCN)(2) coating, polyethylene(5), polyamide(3), TPE(6)/silicone(7)	++EMESA003YR
Abutment Set B Angled abutment 18° with retaining screw, denture cap and black processing insert, retention insert red/orange/green, block-out spacer and parallel post		Titanium alloy(1) with zirconium carbonitride (ZrCN)(2) coating, polyethylene(5), polyamide(3), TPE(6)/silicone(7)	++EMESA003YR
Docklocs bar abutment set Bar abutment with denture cap and black processing insert, retention insert ret/orange/green and block-out spacer		Titanium alloy(1) with zirconium carbonitride (ZrCN)(2) coating, polyethylene(5), polyamide(3), TPE (6)/silicone(7)	++EMESA003YR

All abutments are for single use and are not sterile on delivery.
The products get contact with oral mucosa and saliva.

Validated sterilisation methods:

Method	Procedure	Temperature	Minimum holding time	Drying time
Superheated steam	Vacuum process (3x fractionated pre-vacuum)	134 °C	5 minutes	20 minutes
Superheated steam	Vacuum process (3x fractionated pre-vacuum)	132°C	4 minutes	20 minutes

3.1.2 Matrix system

The matrix system consists of a two-part design, a retention housing that is fixed in the prosthesis and a retention insert made of plastic that transfers the retention force to the abutment via its geometry (detachable snap connection).
For the design of the prosthetic restoration retention housings are available in various designs (geometry, material) and retention inserts in seven different colours.
The colour represents the area of application and the removal force to be achieved. A distinction is made between two areas of application in which the angular difference of the abutments may be up to 20° or up to 40° and between three pull-off forces (retention forces) in light, medium and strong.

Matrix system			
Products	**Picture**	**Material**	**Number Basic UDI-DI**
Standard laboratory set Denture cap with black processing insert, retention inserts blue/pink/clear and block-out spacer		Titanium alloy[1] polyethylene[5], polyamide[3] (PA12), TPE[5]/silicone[6]	++EMESB004Z2
Laboratory set for extended angulation Denture cap with black processing insert, retention inserts red/orange/green and block-out spacer		Titanium alloy[1] polyethylene[5], polyamide[3] (PA12), TPE[5]/silicone[6]	++EMESB004Z2
Bar lab set Denture cap with yellow processing insert, retention inserts blue/pink/clear and block-out spacer		Titanium alloy[1] polyethylene[5], polyamide[3] (PA12), TPE[5]/silicone[6]	++EMESB004Z2
Laboratory set with zirconium denture cap		Zirconium oxide, polyethylene[5] polyamide[3] (PA12), TPE[5]/silicone[6]	++EMESB004Z2
HPP retention inserts		Polyamide12-GB30[3]	++EMESB001YU
Retention inserts standard		Polyamide 6.6[4]	++EMESB001YU
Titanium denture cap with black processing insert		Titanium alloy[1] and PE[5]	++EMESB002YW
Titanium denture cap with yellow processing insert			
Zirconium denture cap with processing insert		Zirconium oxide[13] and PE[5]	++EMESB003YY

All parts of the system are for single use and not sterile on delivery.
The products get contact with oral mucosa and saliva.

Sterilisation method:
Only use disinfectants with tested efficacy (e.g. VAH/DGHM or FDA approval or CE labelling). Always follow the information, instructions and warnings provided by the disinfectant manufacturer.

Validated process for disinfection of products that cannot be sterilised.

Disinfectant: **Cidex® OPA** from JOHNSON & JOHNSON GMBH .
(Cidex® OPA is a registered trademark of Johnson & Johnson)

The medical device must be completely immersed in CIDEX® OPA solution at room temperature (20°C) for a minimum of 5 minutes. It must be ensured that all lumina are completely wetted and all air inclusions are eliminated. Subsequently, the product must be removed from the solution and processed according to the following rinsing protocol.

- After removing the medical device from the CIDEX® OPA solution, immerse it completely in 1 litre of demineralised water. Then rinse the medical device under running water for 30 seconds.

- Repeat both steps, immersion and rinsing, so that the disinfectant is completely removed.

- After the second rinse, carry out a final rinse in isopropanol 70% for 10 seconds.

3.1.3 System tools

The system tools are designed for tightening and loosening Docklocs abutments and retaining screws. The tools are designed with a shaft for rotating dental instruments in accordance with DIN EN ISO 1797-1. In case of the screwdriver with retaining sleeve, the abutment is held on the instrument via the retaining sleeve. They are mechanically driven.

System tool with contra-angle connection			
Products	**Picture**	**Material**	**Number Basic UDI-DI**
Screwdriver for system abutments with shaft for contra-angle connection		Surgical steel (12)	++EMESG00122
Screwdriver with retaining sleeve for Docklocs abutments with shaft for contra-angle connection		Surgical steel(12) and retaining sleeve made of PEEK(8)	++EMESG00224
Hexagonal screwdriver 1.25 mm for Docklocs abutments and Retaining screws with shaft for contra-angle connection		Surgical steel (12)	++EMESG00122
Screwdriver with retaining sleeve for Docklocs Zeramex abutments with shaft for contra-angle connection and ZrCN coating		Surgical steel(12) (ZrCN(2) coating) and retaining sleeve made of PEEK(8)	++EMESG00326

The instruments are intended for repeated use. The products get into short-term contact with the oral mucosa and saliva.

Sterilisation methods:

Method	**Procedure**	**Temperature**	**Minimum holding time**	**Drying time**
Superheated steam	Vacuum process (3x fractionated pre-vacuum)	134 °C	5 minutes	20 minutes
Superheated steam	Vacuum process (3x fractionated pre-vacuum)	132°C	4 minutes	20 minutes

3.1.4 Auxiliary instruments

The universal instruments are designed for changing the retention inserts from the retention housing. The red-gold attachment of the four-part universal instrument is used to manually tighten and loosen the Docklocs abutments. The angle measuring aid is used to determine the angular difference of abutments. It is reusable and used in the oral cavity or on the model.

Auxiliary instruments			
Products	**Picture**	**Material**	**Number Basic UDI-DI**
Universal instrument 2-Piece		Surgical steel (11) (12)	++EMESH00129
Universal instrument 4-Piece		Surgical steel(11) (12)with ZrCN(2)coating and retaining sleeve made of PEEK(8)	++EMESH00129
Angle measuring aid		Surgical steel (10)	++EMESH00129

The instruments are intended for repeated use. The products get into short-term contact with the oral mucosa and saliva.

Validated sterilisation methods:

Method	Procedure	Temperature	Minimum holding time	Drying time
Superheated steam	Vacuum process (3x fractionated pre-vacuum)	134 °C	5 minutes	20 minutes
Superheated steam	Vacuum process (3x fractionated pre-vacuum)	132°C	4 minutes	20 minutes

3.1.5 System accessories

The system accessories such as block-out spacer, laboratory analogs, processing spacer, impression coping with impression cap, parallelization post with black processing insert and the selection abutments are available to the user as auxiliary parts for the prosthetic reconstruction.

System accessories			
Products	**Picture**	**Material**	**Number Basic UDI-DI**
Processing insert / Processing insert for bar		Polyethylene(5)	++EMESK0012W
Processing spacer		Polyoxymethylene (POM)(9)	++EMESK0012W
Impression post		Titanium alloy(1) and polyethylene	++EMESK0022Y
Implant impression coping with retaining screw		Titanium alloy(1)	++EMESK0022Y
Impression cap		Polyoxymethylene (POM)(9)	++EMESK0012W
Parallelization post		Polyethylene(6)	++EMESK0012W
Block-out spacer		Silicone(5)/TPE(6)	++EMESK0012W
Laboratory analog straight		Titanium alloy(1)	++EMESK0022Y
Laboratory analog angled		Titanium alloy(1)	++EMESK0022Y
Scan cap		PEEK MT(8)	++EMESK0012W

All parts of the system accessories are for single use and are not sterile on delivery.
The products, except for the laboratory analogs which are only used in the laboratory, get into short-term contact with oral mucosa and saliva.

Sterilisation methods:
Docklocs retention inserts, processing inserts, block-out ring, parallel posts, retention housing with processing insert and impression copings with processing insert may only be chemically sterilised.
A liquid chemical sterilant approved by the FDA or other appropriate regulatory authority for critical devices that are heat sensitive and incompatible with sterilisation methods such as steam and low temperature gas/steam/plasma processes may be used to sterilise the device in accordance with the manufacturer's instructions.

The sterilisation methods apply to the impression post implant with retaining screw product:

Method	Procedure	Temperature	Minimum holding time	Drying time
Super-heated steam	Vacuum process (3x fractionated pre-vacuum)	135 °C	5 minutes	20 minutes
Super-heated steam	Vacuum process (3x fractionated pre-vacuum)	132°C	4 minutes	20 minutes

3.1.6 Materials used in the products

Titanium alloy											
		Standards	Chemical composition (%(wt) (.))								
			C	AL	V	Y	Fe	O	N	H	Ti
(1)	Titanium Grade 5 Titanium Grade 23 (titanium alloy)	Material no.: 3.7165 EN: TiAl6V4 ELI ISO: 5832-2	max. 0.08	5.50-6.50	3.50-4.50	max. 0.005	max. 0.25	max. 0.13	max. 0.05	max. 0.012	Rest

Coating										
		Abbreviation	Chemical composition (%(wt) (.))							
			Cr + FE	O	C	N	H	Zr		
(2)	Zirconium carbonitride	ZrCN	max. 0.20	max. 0.18	max. 0.50	max. 0.025	max. 0.005	min. 99.2		

Plastics			
		Abbreviation	Remark
(3)	Polyamide 12	PA12-GB30	Polyamide 12 with 30% glass beads
(4)	Polyamide 6.6	PA6.6	Nylon
(5)	Polyethylene	PE	
(6)	Thermoplastic elastomers	TPE	
(7)	Silicone	SI	
(8)	Polyetheretherketone	PEEK	
(9)	Polyoxymethylene	POM	

Surgical steel										
		Standards	Chemical composition (%(wt) (.))							
			C	Si	Mn	P	S	Cr	Ni	N	FE
(10)	1.4301	Material no.: 1.4301 DIN EN 10088-3: X5CrNi 18-10	max. 0.03	max. 1.00	max. 2.00	max. 0.045	max. 0.03	18.0-19.5	10.0-10.5	max. 0.10	Rest

		Standards	Chemical composition (%(wt) (.))										
			C	Si	Mn	P	S	Cr	Ni	Cu	Mo	N	FE
(11)	1.4305	Material no.: 1.4305 DIN EN 10088-3: X8CrNiS18-9	max. 0.10	max. 1.00	max. 2.00	max. 0.045	0.15-0.35	17.0-19.0	8.00-10.00	max. 1.00	max. 0.70	max. 0.10	Rest

		Standards	Chemical composition (%(wt) (.))							
			C	Si	Mn	P	S	Cr	Ni	FE
(12)	1.4035	Material no.: 1.4035 DIN EN 10088-3: X46CrS13	0.43-0.50	max. 1.00	max. 1.00	max. 0.04	max. 0.03	12,5-14.5	max. 1.00	Rest

Zirconium oxide						
		Abbreviation	Chemical composition (%(wt) (.))			
			ZrO_2	Y2O3	Al 2O 3	SiO_2 + Fe_2O_3+ Na_2O
(13)	Zirconium oxide	ZrO_2	90.0-95.0	4.0-10.0	max. 2.00	max. 0.50

3.2. Reference to previous generations

There are no previous variations or variants of the system.

3.3. Accessories parts

There are no additional accessories.

3.4. Products that are used in combination with the product.

Docklocs abutments are available for the implant systems listed in the table below.

Table 1: Compatible Implant Systems

Implant system
Straumann®
Bone Level NC
Bone Level RC
Tissue Level NNC
Tissue Level RN
Tissue Level WN
LOGON®
LOGON 3.3mm
LOGON 3.8mm
LOGON 4.3mm
LOGON 5.0mm
Camlog®
iSy®
Camlog® Ø3.3mm
Camlog® Ø3.8mm
Camlog® Ø4.3mm
Camlog® Ø5.0mm
Conelog® Ø3.3mm
Conelog® Ø3.8mm
Conelog® Ø4.3mm
Conelog® Ø5.0mm
MegaGen
AnyRidge®
AnyOne® Onestage
AnyOne® Internal
AnyOne® mini
BLUEDIAMOND® NC
BLUEDIAMOND® RC
Botticelli
Botticelli small
Botticelli regular
Bego
Sub-Tec S / RI / RS / RSX 3.75mm-4.1mm
Sub-Tec S / RI / RS / RSX 4.5mm
OSSTEM®/ HiOssen Implant®
TS System Mini (yellow)/ET System Mini (yellow)
TS System Regular (green)/ET System Regular (green)
NEODENT®
Grand Morse®
Champions
Champions (R)evolution®
Dyna Dental®
Helix
Medentis®
ICX
Dentsply Sirona®
Astra OsseoSpeed® TX Aqua 3.5mm/4mm
Astra OsseoSpeed® TX Lilac 4.5mm/5mm
Astra OsseoSpeed® Profile EV 3.6mm
Astra OsseoSpeed® Profile EV 4.2mm
Astra OsseoSpeed® Profile EV 4.8mm
Ankylos® C/X
Nobel Biocare®
NobelReplace® Tri-Channel 3.5mm
NobelReplace® Tri-Channel 4.3mm

NobelReplace® Tri-Channel 5.0mm
NobelActive® Conical NP
NobelActive® Conical RP
Brånemark System® External Hex NP
Brånemark System® External Hex RP
Brånemark System® External Hex WP
ZimVie®
Tapered Screw-Vent® 3.5mm
Tapered Screw-Vent® 4.5mm
Tapered Screw-Vent® 5.7mm
3i External Hex NP 3.25mm/3.4mm
3i External Hex RP 4.1mm
3.4mm Certain® Connection
4.1mm Certain® Connection
BioHorizons®
Tapered Internal Implant System 3.5mm
Tapered Internal Implant System 4.5mm
Tapered Internal Implant System 5.7mm
LASAK
BioniQ Regular
BioniQ Narrow
Bredent Medical
SKY®
copaSKY®
Southern Implants®
External Hex Ø 3,0mm
External Hex Ø 3,25mm
External Hex Ø 4,0mm
External Hex Ø 5,0mm
Deep Conical Ø 3,0mm
Deep Conical Ø 3,5/4,0mm
Deep Conical Ø 5,0mm
Tri Nex® Ø3,5mm
Tri Nex® Ø4,3mm
Tri Nex® Ø5,0mm
SP1
Internal Hex/Provata®
Internal Provata®, Ø 3,3 mm
IT Connection Ø4,8mm
C-Tech Implant
EL/Esthetic Line
Products marked with ® are registered trademarks of the corresponding manufacturer.

4. Risks and Warnings

4.1. Remaining risks and undesirable effects

Implantology and prosthetics cannot be considered separately from each other.
Dental procedures can cause side effects such as bleeding, haematomas and infections.
Other side effects can include inflammatory reactions (mucositis, peri-implantitis) in the soft tissue.
The materials used can trigger side effects in patients with intolerances in the form of an allergic reaction, which can manifest itself locally in the form of stomatitis, lichen ruber planus, gingivitis or periodontitis.
For sensitive patients, inserting and removing the abutments can trigger a gag reflex (pharyngeal reflex).

4.1.1 Quantitative data

4.1.1.1 Docklocs Attachment System

Source	Results	Valuation
Customer surveys	The analyses of the customer surveys conducted from 2018 to 2025 on the Docklocs Attachment System did not identify any new risks.	No recognisable risk
Complaints	Since 2018 to 2025, there have been no complaints that indicate a risk to product safety.	No recognisable risk

4.1.1.2 Locator Attachment System

Literature research:

The literature search conducted in PubMed/PubMed Central, DIMDI, BfArM, Google Scholar Central and Maude databases for the past 12 months yielded the following results. Results in which the search term could be assigned to the subject area Docklocs Attachment System were analysed.

Database	Hits (number)	Type of register / data collection	Considered	The following are considered relevant	Risk justifiable	
					Yes	no
PubMed	612	Prospective / Retrospective	20	4	x	
DIMDI	No results	Retrospective				
BfArM	No results	Retrospective				
Google Scholar	569	Prospective / Retrospective	12	3	x	
Maude	157	Retrospective	157	0	x	

Detailed analysis of literature in Chapter 5.

Conclusion
The literature research shows that there are no known high-risk factors for the patient due to the Locator System and that the benefits for the patient far outweigh the risks. The Docklocs Attachment System builds on the Locator System and increases user and patient satisfaction through further developments.

The remaining risk associated with the use of the medical device is low after evaluation of the data available.

4.2. Warnings and Precautions

4.2.1 Warnings and Precautions

The product should be checked for integrity before use. Products in damaged packaging should not be used on patients. If the packaging is damaged, the damaged packaging should be returned to the manufacturer together with the product. Replacement will only be provided if the damage was caused by shipping process.
If the Docklocs Implant Abutment is exposed to inappropriate loading conditions, there is a potential risk of metal fatigue.

As surgical instruments are susceptible to damage and wear, they should be checked before each use. Markings should be visible and legible. To ensure proper function, any reusable instrument should be replaced as soon as damage or wear occurs. The number of uses varies and depends on a variety of factors including, but not limited to, the bone density found, handling, proper cleaning, exposure to the autoclave and storage conditions (do not store tools or instruments under wet conditions). Over time, repeated sterilisation may affect the appearance and visibility of the markings. If this applies to the surgical instrument, check the connection function for wear to ensure that the connection is not damaged.

Assessment of the patient, including determination of general health, oral hygiene habits and oral hygiene status, motivation for good dental care and anatomical acceptance are critical prior to placement of implant fixtures as part of the restorative process. A comprehensive assessment of the patient's medical status and medical history is mandatory. Treatment planning is critical to the success of the implant and prosthesis.

Always observe the implant manufacturer's instructions for use! Some implant manufacturers only allow a divergence of 10° per implant to avoid excessive mechanical stress.

The use of this attachment system requires that the clinician be familiar with the product and the method for its use and application. The clinician must exercise sound judgement in deciding when and where to use the product.

The individual patient situation should always be considered when carrying out the prosthetic restoration. If parafunctions or temporomandibular joint disorders such as bruxism are known, these must be taken into consideration during treatment.

4.2.2 MRI Safety Information

The Docklocs Attachment System has not been tested for safety and compatibility in the magnetic resonance (MR) environment. It has not been tested for heating, migration or image artefacts in the MR environment. The safety of the Docklocs Attachment System in the MR environment is unknown. Scanning a patient wearing this attachment system may cause injury to the patient.

4.2.3 Storage and Handling

For the Docklocs Attachment System, which is in its original undamaged packaging, there are no special considerations regarding transport and handling. It should be stored in a dry place at room temperature and protected from direct sunlight.

4.2.4 Single-Use Products

Except for tools and instruments, the components of the Docklocs Attachment System are all single-use products and are not sterile on delivery. Single-use devices must not be reused or resterilised. If a single-use device is reused, the patient may be harmed by the transfer of blood, tissue or saliva that may contain infectious diseases. Single-use devices that are resterilised may not function as intended and may result in improper surgical intervention and malfunction or failure of the device.

Docklocs retention inserts: Docklocs retention inserts that are accidentally reused may result in loss of retention of the overdenture due to wear from previous use or damage during removal with the Docklocs universal instrument.

Docklocs Attachments: Docklocs attachments that are accidentally reused could cause patient contamination, debris build-up and subsequent wear of the retention inserts. This would lead to improper fit and malfunction, resulting in loss of retention of the prosthesis.

4.2.5 Disposal

Dispose of used devices that pose a risk of infection in accordance with the hospital waste procedures applicable to the facility and applicable to local and state regulations.

4.2.6 Performance Requirements and Limitations

4.2.6.1 Compatibility

The abutments of the Docklocs Attachment System may only be combined with the implant systems they are intended for.
Check whether the products are compatible using the labelling on the products or product labels.
The implant systems compatible with the abutments are listed in the table:
Table 1: Compatible Implant Systems

4.2.6.2 Performance

To achieve the desired performance of the Docklocs Attachment System, only products listed in the instructions for use may be combined with each other. Each product may only be used in accordance with its intended use. All parameters specified in the instructions for use that are relevant for the respective product must be observed.

4.2.7 Patient Care

Good oral hygiene is crucial for success with the Docklocs Attachment System. The patient's attention should be drawn to the following:

- Docklocs attachments must be thoroughly cleaned every day to prevent the build-up of plaque. The patient should use a soft nylon brush or a toothbrush with an end tuft with a non-abrasive toothpaste to clean the abutments.
- The The coarse particles in abrasive toothpastes can damage the surfaces of the abument. Scratched abutments can lead to increased plaque accumulation.
- A rinsing system is recommended to remove residues from the inside of the Docklocs retention inserts.
- The Docklocs retention inserts are made from a flexible plastic material so that the overdentures can be removed and replaced regularly. Plastic materials are subject to a certain amount of wear during normal use and may need to be replaced.
- Bruxism (teeth grinding) wears out the Docklocs abutments and can shorten the service life of the retention inserts.

Patients should be instructed to make routine follow-up visits for hygiene and to assess the luting function. If a patient experiences discomfort or loss of retention of the overdenture, they should consult a dentist.
Follow-up visits are recommended at 6-month intervals. The abutments must be retightened at follow-up visits according to the torque specifications given above. Failure to retighten the abutments may result in loosening of the screws and fracture of the abutment. Patients should be examined at each follow-up visit for signs of inflammation around the implant abutments and for implant mobility.

4.2.8 Further Information

Conventional restorative protocols should be followed when incorporating the attachments into the patient's overdenture. At each restoration standard care and maintenance of the overdenture should be followed to ensure the longevity.

4.3. Other Relevant Safety Aspects

No further safety measures are required.

5. Summary of the Clinical Evaluation According to Annex XIV

5.1. Summary of Clinical Data on an Equivalent Product

The equivalence to the original manufacturer Zest Anchors was analysed as a reference. A further equivalence analysis is not necessary, as all systems established on the market are generics of the original locator system from Zest Anchors. No SSCP is yet available for the Locator System. The Locator System was introduced in 2001. Many years of clinical experience and in-depth documentation on the system is available.
Many studies and publications show that this system has many advantages for removable prosthesis fixation on implants compared to other systems such as ball anchors and magnetic fixation.
Clinical data from equivalent and CE-marked devices can be used to demonstrate the efficacy and safety of a medical device. According to Annex A1 of MEDDEV 2.7 / 1 (Rev. 04) and Annex XIV (Part A) of MDR 2017/745, equivalence is based on clinical, technical and biological aspects. The equivalence assessment was carried out in the clinical evaluation.

All relevant data were obtained from studies, instructions for use, surgical and/or prosthetic manuals as well as system overviews and product catalogues of the manufacturer. The summarised data show that there are no differences between the Docklocs products under evaluation and the corresponding Locator System products that have a significant impact on clinical efficacy and safety.

In conclusion, the literature research carried out does not provide any indications of an increased risk for the Locator System from Zest. The information obtained for the Locator System from the studies and publications can be transferred to the Docklocs System. Many studies show that the Locator System is the preferred solution for the fixation of overdentures or partial dentures that are fully or partially supported by endosseous implants in the mandible or maxilla.
The Locator System represents a new type of supply and has significant advantages over other fastening systems on the market. The comparison between the locator system and the ball head system in particular shows that the locator system has better results than the ball head system in terms of wear and retention force/retention loss has (Upinder S, Saluja BS, Gupta G, Kaur B, Singh G.; Comparison of changes in retentive force and wear pattern of two stud attachments for implant overdentures: An *in vitro* study. Indian J Dent Sci 2019;11:65-70).
Most criticized in many studies is the rapid loss of retention between the prosthesis and the retaining elements. This is also shown by a study that determines the satisfaction of patients who are fitted with a ball head and Locator System. The rapid loss of retention can have many causes and is rated as very negative. The different materials of the components play a major role, how the practitioner has carried out the work, with two or four implants and how divergent the implants are placed in relation to each other. There are already several studies that show how much influence these factors have on wear and loss of retention. Finally, the patient's behaviour in terms of prevention and care also influences wear. However, the material of the retention inserts certainly has a major influence on wear behaviour. This was also shown in the investigations in the technical documentation between the Zest retention inserts and the Docklocs retention inserts. It was found that the retention inserts from Zest had a very strong loss of retention after 1000 cycles, which simulates a wearing time of a prosthesis of approximately one year. This behaviour was not observed with the Docklocs retention inserts, which had a linear progression of retention loss over the required 5000 cycles and still showed a comparably high retention force afterwards.
Many studies show that the practitioner also has a major influence on the success of a locator treatment. The practitioner is supported by the MEDEALS instructions for use and working instructions. Further studies show the major influence of axial divergences between implants in locator restorations. This leads to premature loss of retention of the plastic inserts

and increased wear of the abutments. As this cannot always be avoided, it is even more important that MEDEALIS, with its 18° angled abutments, enables the practitioner to compensate larger axial divergence as far as possible.

5.2. Summary of Clinical Data from Device-Tests Performed Prior CE-Marking

Medealis maintains extensive development documentation for its products. The products were tested and evaluated for their strength and compatibility with the connection geometries. The materials were analysed and evaluated for their biocompatibility. Tests were carried out to verify the durability and function of the retention inserts.
The data obtained is stored in the development documentation and the technical documentation.

As part of vigilance, the BfArM database (Federal Institute for Drugs and Medical Devices) is searched once a month for specific problems that could have an impact on the Docklocs attachment system.

Investigation period: monthly since January 2020

Search terms: **Locator, Abutment, Retention insert, Retention housing, Dental instrument, Dental, Implant**

The terms **implant and dental** are included to broaden the scope of the search.

For the term **implant**, only results with a dental reference are included.

No clinical data could be identified that has influence on the safety of the Docklocs attachment system.

5.3 Summary of Clinical Data from External Sources

5.3.1 Literature research

Since 2018, a comprehensive literature search has been conducted annually in scientific databases.
In 2018, a literature search was conducted on the state of the art implant prosthetics for the development of the Docklocs Attachment System.
Furthermore, the following literature research was conducted and the relevance to the Docklocs attachment system was assessed.

	Literature analysed	Valuation
Literature research state of the art from 28/04/2018	86 Publications	Incorporated into the development of the Docklocs Attachment System
Literature research 29/06/2018	26 publications assessed of which 20 were considered relevant	From the research, there is no recognisable indication of an increased risk with the Docklocs Attachment System
Literature research 17.06.2019	53 publications assessed of which 28 were considered relevant	From the research, there is no recognisable indication of an increased risk with the Docklocs Attachment System

Literature research 18/03/2020	48 publications assessed of which 36 were considered relevant	From the research, there is no recognisable indication of an increased risk with the Docklocs Attachment System
Literature research 28.06.2021	61 publications assessed of which 13 were considered relevant	From the research, there is no recognisable indication of an increased risk with the Docklocs Attachment System
Literature research 01.07.2022	31 publications assessed of which 17 were considered relevant Additional analysis of the Maude database for anomalies in reported user problems with Locator abutments. The period 01.01.2021-01.07.2022 was considered 208 incidents were reported	From the research, there is no recognisable indication of an increased risk with the Docklocs Attachment System. The advanced search in the Maude database shows incidents where a clear assignment to the Docklocs Attachment System is not possible.
Literature research 20.06.2023	31 publications assessed of which 11 were considered relevant Additional examination of the Maude database for anomalies in reported user problems with Locator abutments. The period 07.2022-06.2023 was analysed 64 incidents were reported	From the research, there is no recognisable indication of an increased risk with the Docklocs Attachment System. The advanced search in the Maude database shows incidents where a clear assignment to the Docklocs Attachment System is not possible.
Literature research 02.06.2024	31 publications assessed of which 14 were considered relevant Additional examination of the Maude database for anomalies in reported user problems with Locator abutments. The period 07.2023-06.2024 was analysed 149 incidents were reported	From the research, there is no recognisable indication of an increased risk with the Docklocs Attachment System. The advanced search in the Maude database shows incidents where a clear assignment to the Docklocs Attachment System is not possible.
Literature research 02.06.2025	32 publications assessed of which 7 were considered relevant Additional examination of the Maude database for anomalies in reported user problems with Locator abutments. The period 07.2023-06.2024 was analysed 157 incidents were reported	From the research, there is no recognisable indication of an increased risk with the Docklocs Attachment System. The advanced search in the Maude database shows incidents where a clear assignment to the Docklocs Attachment System is not possible.

5.3.2 PMS Data

Medealis has established a post-market surveillance system in accordance with Article 83 MDR.
In addition to analysing the literature, proactive measures are taken to ensure product safety. Medealis maintains close contact with its customers. In addition to analysing customer discussions about users' experiences with the Docklocs Attachment System, a customer survey is conducted once a year which includes an evaluation of the products by the user. Suggestions from users are considered and incorporated into the system if possible.
Medealis operates an active complaints management system from which information is obtained and evaluated. Product quality tests are constantly carried out on the products.
All analyses of the PMS show that no unacceptable risk can be derived for the Docklocs attachment system at the present time and that the benefits for the patients are predominant to the risks.

5.4 Overall Summary of Clinical Performance and Safety

The clinical evaluation includes all Medealis products listed in the declaration of conformity. The medical devices are manufactured according to state of the art technology, the materials used are tested for their suitability and fulfil all requirements of DIN 10993-1 regarding biocompatibility. Working instructions for professional groups, instructions for use and cleaning instructions are available for the user, to ensure safe handling of all products. The products are tested for strength and compatibility.
The products are subjected to continuous testing and product specification underly extensive control.
The intended use of each product is clearly specified.
The products or raw materials and components were not manufactured using materials of animal or human origin.
The safety and performance requirements were analysed.
The Docklocs Attachment System fulfils all requirements for clinical performance and safety.

5.5 Ongoing or Planned Clinical Follow-up Studies Post Market Launch

A PMCF plan is drawn up for clinical follow-up and is updated every year or as required. This PMCF plan is used to determine the activities required to ensure the clinical performance and safety of the products. The plan was created on 12.04.2025. The PMCF evaluation report was prepared on 30/05/2025.

5.6 Status of the Product in Terms of Benefit/Risk Compared to Alternatives

Alternative products were listed in the clinical evaluation as well as their advantages and disadvantages. The study situation is clear regarding the Locator System, which can also be applied to the Docklocs Attachment System. In the field of elastic anchorage of removable partial or full dentures on osseointegrated dental implants, the Locator System is regarded as the leading system. The benefit for the patient in relation to the possible risk has been proven by many studies.

6. Possible Diagnostic or Therapeutic Alternatives

There are alternative attachment systems for attaching full dentures to dental implants. These include ball attachments, magnetic attachments, bar attachments and telescopic attachments.
The individual patient situation should always be considered when carrying out the prosthetic restoration.

The Docklocs Attachment System is state of the art for attaching a full denture to dental implants. Compared to alternative products, the benefit/risk ratio shows that there is a benefit for the patient and no increased risk is recognisable.

7. Proposed Profile and Training for Users

The use of this attachment system requires the clinician to be familiar with the product and the method for its use and application. The clinician must exercise sound judgement in deciding when and where to use the product.
The dentist/doctor should have knowledge of implantology. In addition, in related disciplines such as surgery, periodontology, prosthetics, as the finished work must have long-term function and aesthetics.

8. Reference to All Applied Harmonised Standards and CS

No.	1.1.3.1.1.1 Law / Regulation / Standard	Version from
	Relevant requirements for medical devices (directives/laws/regulations)	
1	Act on Medical Devices (Medical Devices Implementation Act - (MPDG))	28.04.2021 (version dated 12.05.2021)
3	Medical Devices EU Adaptation Act / National Regulations on the Medical Devices Ordinance (MPEUAnpG)	26.05.2021
4	Ordinance on the Reporting of Suspected Serious Incidents involving Medical Devices (Medical Device User Notification and Information Ordinance - MPAMIV)	21.04.2021
5	Regulation (EU) 2017/745 (MDR)	05.04.2017 (Version from 10 January 2025)
	Requirements in the area of quality management/medical devices (standards)	
6	DIN EN ISO 9001:2015 - Quality management systems	Nov. 2015
7	DIN EN ISO 13485:2021 - Quality management systems - Requirements for regulatory purposes (German version)	Dec. 2021
8	DIN EN ISO 14971:2022-04- Medical devices - Application of risk management to medical devices	April. 2022
9	DIN EN ISO 15223-1:2022-02 Medical devices - Symbols to be used on medical device labels, labelling and information to be provided.	Feb. 2022
10	ISO 20417:2021-04 Medical devices - Requirements for information to be provided by the manufacturer (German version)	April 2021
11	DIN EN ISO 10993-1:2021-05 - Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management system	May 2021

12	DIN EN 62366:2021-08 - Medical devices - Application of fitness for purpose to medical devices	July 2021
	Guidelines in the area of quality management/medical devices (MEDDEV)	
13	MDCG 2023-3 Rev. 2 Questions and Answers on vigilance terms and concepts as outlined in the Regulation (EU) 2017/745 and Regulation (EU) 2017/746 *Replaces MEDDEV 2.12-1*	Oct. 2022
13a	MDCG 2024-1 Guidance on the vigilance system for CE-marked devices	Jan. 2024
13b	MDCG 2020-10/1_Rev.1 Safety reporting in clinical investigations of medical devices under EU 2017/745 *Regulation of the reporting of serious adverse events (SAEs) and product defects in the context of clinical trials*	Oct. 2022
14	MEDDEV 2.12-2 - Guidelines on medical devices - ON POST MARKET CLINICAL FOLLOW-UP STUDIES *Remains partially relevant as a reference document*	Rev.2 2012-01
14a	MDCG 2020-7 PMCF Plan Template *Expand and specify MEDDEV 2.12-2*	April 2020
14b	MDCG 2020-8: PMCF Evaluation Report Template *Expand and specify MEDDEV 2.12-2*	April 2020
15	MEDDEV. 2.7/1 CLINICAL EVALUATION: A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES *Is not replaced, but supplemented and updated by items 15a-15g*	Rev.4 2016-06
15a	MDCG 2019-9_Rev.1 Summary of safety and clinical performance	March 2022
15b	MDCG 2020-1 Guidance on Clinical Evaluation	March 2020
15c	MDCG 2020-5 Clinical Evaluation - Equivalence	April 2020
15d	MDCG 2020-6 Clinical evidence needed for legacy devices	April 2020
15e	MDCG 2020-13 Clinical evaluation assessment report template	July 2020
15f	MDCG 2021-28 Substantial modification of clinical investigation under Medical Device Regulation	Dec. 2021
15g	MDCG 2023-7: Guidance on exemptions from the requirement to perform clinical investigations	Dec. 2023
16	DIN EN ISO 14801:2017-03 Fatigue tests	2017-03
17	DIN EN ISO 5832-3:2022 (Surgical implants - Metallic materials - Part 3: Titanium 6-aluminium 4-vanadium wrought alloy)	Feb. 2022
18	EN ISO 17664:2021-11 (Reprocessing of healthcare products - Information to be provided by the manufacturer of a medical device)	Nov. 2021
19	DIN EN ISO 22674:2023-4 (Dentistry - Metallic materials for fixed and removable dental prostheses and appliances)	April. 2023
20	DIN EN ISO 11737-1:2021-10 Sterilisation of health care products - Microbiological methods - Part 1: Determination of the population of microorganisms on products (ISO 11737-1:2018); German version EN ISO 11737-1:2018	Oct. 2021
21	DIN ISO 2859-1:2014-08 Acceptance sampling inspection based on the number of defective units or defects (attribute inspection)	Aug. 2014
	Further guidelines of the MDCG	
22	MDCG 2021-24 Guidance on classification of medical devices	Oct. 2021
23	MDCG 2022-14 MDCG Position Paper Transition to the MDR	Aug. 2022
24	MDCG 2019-15 rev.1 GUIDANCE NOTES FOR MANUFACTURERS OF CLASS I MEDICAL DEVICES	July 2020 Rev. 1
25	MDCG 2019-11 Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 - MDR	Oct: 2019
26	MDCG 2019-7 Rev.1 Guidance on Article 15 of the medical device regulation (MDR) and in vitro diagnostic device regulation (IVDR) on a 'person responsible for regulatory compliance' (PRRC)	Dec. 2023

27	MDCG 2022-21 GUIDANCE ON PERIODIC SAFETY UPDATE REPORT (PSUR) ACCORDING TO REGULATION (EU) 2017/745 (MDR)	Dec. 2022

9. History of the revision

SSCP Revision number	Date of the exhibition	Change description	Revision validated by the notified body
01	28.02.2022	Creation	☐ Yes Language of validation: **German** ☒ No
02	20.07.2022	Revision of the SSCP report according to the requirements of the Notified Body.	☒ Yes Language of validation: **German** ☐ No
03	27.06.2023	Update	☐ Yes Language of validation: **German** ☒ No
04	20.06.2024	Update	☐ Yes Language of validation: **German** ☒ No
05	30.05.2025	Updating of all relevant safety and performance information. English translation added.	☐ Yes Language of validation: **German** ☒ No