TF.01_2.2-2.1 / Ver. 5.0 / English
Date of update: 20 October 2022

SOLVO UK
DENTAL IMPLANT

Straight Abutment and Angled Abutment

Instructions for use

Important: Please read.

Description

A premanufactured dental implant abutment to be directly connected to an endosseous dental implant intended for use as an aid in prosthetic rehabilitation.
Straight Abutment and Angled Abutment are made of Grade 5 Titanium.
Straight Abutment and Angled Abutment are available for use with the SOLVO UK Implant Systems treatment concept with guided surgery only.

Disclaimer of liability

This product is part of an overall concept and may only be used in conjunction with the associated original products according to the instructions recommendation of SOLVO Implant. Non-recommended use of products made by third parties in conjunction with SOLVO Implant products will void any warranty or other obligation, express or implied, of SOLVO Implant.
The user of SOLVO Implant products has the duty to determine whether or not any product is suitable for the particular patient and circumstances.
SOLVO Implant disclaims any liability, express or implied, and shall have no responsibility for any direct, indirect, punitive or other damages, arising out of or in connection with any errors in professional judgment or practice in the use of SOLVO Implant products. The user is also obliged to study the latest developments in regard to this SOLVO Implant product and its applications regularly. In cases of doubt, the user has to contact SOLVO Implant.
Since the utilization of this product is under the control of the user, it is his/her responsibility. SOLVO Implant does not assume any liability whatsoever for damage arising thereof.

Please note that some products detailed in this Instruction for Use may not be regulatory cleared, released or licensed for sale in all markets.

Intended Use

Dental implant abutments are intended to be used in the upper or lower jaw and used for supporting tooth replacements to restore chewing function.

The abutments in combination with two-stage endosseous implants are used as the foundation for anchoring tooth replacements in either jaw. Restorations range from replacing one single tooth to fixed partial dentures using cement-retained supra-constructions.

Indications

Straight Abutments and Angled Abutments are pre-manufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation.

Contraindications

It is contraindicated to use abutments in:
- Patients who are medically unfit for an oral surgical procedure.
- Patients in whom adequate sizes, numbers or desirable positions of implants are not reachable to achieve safe support of functional or eventually parafunctional loads.
- Patients who are allergic or hypersensitive to commercially or Titanium.

Cautions

Pre-operative hard tissue or soft tissue deficits may yield a compromised esthetic result or unfavorable implant angulations.
To secure the long-term treatment outcome it is advised to provide comprehensive regular patient follow up after implant treatment and to inform about appropriate oral hygiene.
All instruments and tooling used in surgery must be maintained in good condition and care must be taken that instrumentation does not damage implants or other components.
Special attention has to be given to patients who have local or systemic factors that could interfere with the healing process of either bone or soft tissue or the osseointegration process (e.g., cigarette smoking, poor oral hygiene, uncontrolled diabetes, oro-facial radiotherapy, steroid therapy, infections in the neighboring bone).
Special caution is advised in patients who receive bisphosphonate therapy.
In general, implant placement and prosthetic design must accommodate individual patient conditions. In case of bruxism or unfavorable jaw relationships reappraisal of the treatment option may be considered.
Because of the small size of the devices, care must be taken that they are not swallowed or aspirated by the patient.
Products in damaged packages should not be used on the patient.

Users

Dental implant surgery requires appropriate and adequate training.
It is strongly recommended that clinicians, new as well as experienced implant users, always go through special training before undertaking a new treatment method.
Close cooperation between surgeon, restorative dentist and dental laboratory technician is essential for a successful implant treatment.

Handling Instructions

Modifications of abutments could be performed using copious water irrigation.
Extra-oral modification of abutment is recommended.

Clinical Procedure:

1. Select appropriate abutment and check occlusal clearance.
2. Connect and tighten the abutment. It is recommended to verify the final abutment seating using radiographic imaging.
3. Tighten the abutment using Abutment Screw with Driver Torque 1,2 and Adjustable Torque Wrench prosthetic.

Caution: Care should be taken when trying to insert the screw. It is important that it is correctly placed. Never exceed recommended maximum tightening torque for the abutment screw. Overtightening of abutment may lead to a screw fracture.

Note: Use the appropriate torque values for the abutments. Torque values; Standard 30 Ncm, Mini 20 Ncm, Ultra Mini 15 Ncm.

Materials

All Straight Abutments and Abutment Screws: Grade 5 Titanium.
All Angled Abutments and Abutment Screws: Grade 5 Titanium.

Cleaning and sterilization instructions

Straight Abutments and Angled Abutments are delivered non-sterile for single use and must be autoclave sterilization at 121° C- 20 min prior to use.
Warning: Use of non-sterile device may lead to infection of tissues or infectious diseases.
Caution: Straight Abutment and Angled Abutment are single-use products that must not be reprocessed. Reprocessing could cause loss of mechanical, chemical and / or biological characteristics. Re-use could cause cross contamination.
Warning: The Abutment System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment.
The safety of Abutment System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Storage and handling

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 device characteristics leading to failure.

Disposal

Disposal of the device shall follow local regulations and environmental requirements, taking different contamination levels into account.

CE 1984	Notified body number		Do not re-use
REF	Reference number		Consult electronic instructions for use
LOT	Lot number	NON STERILE	Sterile (121° C- 20 min.)
	Production date		Manufacturer Name/ Manufacturer Address
EC REP	Authorized representative in the European Community	MD	Medical Device

Manufacturer: SOLVO UK IMPLANTS CO. LTD.
Address: 60 Millmead Business Center Mill Mead Road N17 9QU LONDON/ENGLAND
E-Mail: info@solvodental.com
Web: www.solvoimplants.com

EC REP **EU Authorized Representative:**
MDSS GmbH
Address: Schiffgraben 41, 30175 Hannover, Germany

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Date of update: 20 October 2022

SOLVO UK
DENTAL IMPLANT

Ball Attachment

Instructions for use

Important: Please read.

Description

A premanufactured dental implant abutment to be directly connected to an endosseous dental implant intended for use as an aid in prosthetic rehabilitation.
Ball Attachments are made of Grade 5 Titanium.
Ball Attachments are available for use with the SOLVO UK Implant Systems treatment concept with guided surgery only.

Disclaimer of liability

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The user of SOLVO Implant products has the duty to determine whether or not any product is suitable for the particular patient and circumstances.
SOLVO Implant disclaims any liability, express or implied, and shall have no responsibility for any direct, indirect, punitive or other damages, arising out of or in connection with any errors in professional judgment or practice in the use of SOLVO Implant products. The user is also obliged to study the latest developments in regard to this SOLVO Implant product and its applications regularly. In cases of doubt, the user has to contact SOLVO Implant.
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Please note that some products detailed in this Instruction for Use may not be regulatory cleared, released or licensed for sale in all markets.

Intended use

Dental implant abutments are intended to be used in the upper or lower jaw and used for supporting tooth replacements to restore chewing function.

The abutments in combination with two-stage endosseous implants are used as the foundation for anchoring tooth replacements in either jaw.
Ball Attachments are intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.

Indications

Ball Attachments are pre-manufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation.

Contraindications

It is contraindicated to use abutments in:
- Patients who are medically unfit for an oral surgical procedure.
- Patients in whom adequate sizes, numbers or desirable positions of implants are not reachable to achieve safe support of functional or eventually parafunctional loads.
- Patients who are allergic or hypersensitive to commercially or Titanium.

Cautions

Pre-operative hard tissue or soft tissue deficits may yield a compromised esthetic result or unfavorable implant angulations.
To secure the long-term treatment outcome it is advised to provide comprehensive regular patient follow up after implant treatment and to inform about appropriate oral hygiene.
All instruments and tooling used in surgery must be maintained in good condition and care must be taken that instrumentation does not damage implants or other components.
Special attention has to be given to patients who have local or systemic factors that could interfere with the healing process of either bone or soft tissue or the osseointegration process (e.g., cigarette smoking, poor oral hygiene, uncontrolled diabetes, oro-facial radiotherapy, steroid therapy, infections in the neighboring bone).
Special caution is advised in patients who receive bisphosphonate therapy.
In general, implant placement and prosthetic design must accommodate individual patient conditions. In case of bruxism or unfavorable jaw relationships reappraisal of the treatment option may be considered.
Because of the small size of the devices, care must be taken that they are not swallowed or aspirated by the patient.
Products in damaged packages should not be used on the patient.

Users

Dental implant surgery requires appropriate and adequate training.

It is strongly recommended that clinicians, new as well as experienced implant users, always go through special training before undertaking a new treatment method.
Close cooperation between surgeon, restorative dentist and dental laboratory technician is essential for a successful implant treatment.

Handling Instructions

Modifications of abutments could be performed using copious water irrigation.
Extra-oral modification of abutment is recommended.

Clinical Procedure:

1. Select appropriate abutment and check occlusal clearance.
2. Connect and tighten the abutment. It is recommended to verify the final abutment seating using radiographic imaging.
3. Tighten the abutment using Driver Torque 1,2 and Adjustable Torque Wrench prosthetic.

Caution: Use of higher torque values than recommended could cause a fracture of the abutment.

Note: Use the appropriate torque values for the abutments.
Torque values; Standard 25 Ncm, Mini 20 Ncm, Ultra Mini 15 Ncm.

Materials

All Ball Attachment: Grade 5 Titanium.
Ball Attachment Metal Cap: Grade 5 Titanium.
Ball Attachment Caps: Polyamide 6.6.
Retentive Ring: Polyamide 6.6.

Cleaning and sterilization instructions

Ball Attachments are delivered non-sterile for single use and must be autoclave sterilization at 121˚C- 20 min prior to use.
Warning: Use of non-sterile device may lead to infection of tissues or infectious diseases.
Caution: Ball Attachment is a single use product that must not be reprocessed. Reprocessing could cause loss of mechanical, chemical and / or biological characteristics. Re-use could cause cross contamination.
Warning: The Abutment System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of Abutment System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Storage and handling

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 device characteristics leading to failure.

Disposal

Disposal of the device shall follow local regulations and environmental requirements, taking different contamination levels into account.

CE 1984	Notified body number		Do not re-use
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LOT	Lot number	NON STERILE	Sterile (121˚C- 20 min.)
	Production date		Manufacturer Name/ Manufacturer Address
EC REP	Authorized representative in the European Community	MD	Medical Device

Manufacturer: SOLVO UK IMPLANTS CO. LTD.
Address: 60 Millmead Business Center Mill Mead Road N17 9QU LONDON/ENGLAND
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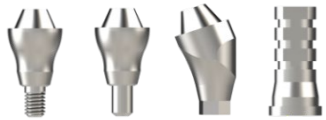
Date of update: 20 October 2022

SOLVO UK
DENTAL IMPLANT

Multi-Unit Straight / Angled Abutment and Multi Unit Titanium Abutment



Instructions for use

Important: Please read.

Description

A premanufactured dental implant abutment to be directly connected to an endosseous dental implant intended for use as an aid in prosthetic rehabilitation.
Multi Unit Straight/Angled Abutment and Multi Unit Titanium Abutment are made of Grade 5 Titanium.

Multi Unit Straight/Angled Abutments and Multi Unit Titanium Abutments are available for use with the SOLVO UK Implant Systems treatment concept with guided surgery only.

Disclaimer of liability

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Intended use

Dental implant abutments are intended to be used in the upper or lower jaw and used for supporting tooth replacements to restore chewing function.
The abutments in combination with two-stage endosseous implants are used as the foundation for anchoring tooth replacements in either jaw.
Multi Unit Abutments are intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.

Indications

Multi Unit Straight/Angled and Titanium Abutments are a premanufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation.

Contraindications

It is contraindicated to use Multi Unit Abutments in:
- Patients who are medically unfit for an oral surgical procedure.
- Patients in whom adequate sizes, numbers or desirable positions of implants are not reachable to achieve safe support of functional or eventually parafunctional loads.
- Patients who are allergic or hypersensitive to commercially or Titanium.

Cautions

Pre-operative hard tissue or soft tissue deficits may yield a compromised esthetic result or unfavorable implant angulations.
To secure the long-term treatment outcome it is advised to provide comprehensive regular patient follow up after implant treatment and to inform about appropriate oral hygiene.
All instruments and tooling used in surgery must be maintained in good condition and care must be taken that instrumentation does not damage implants or other components.
Special attention has to be given to patients who have local or systemic factors that could interfere with the healing process of either bone or soft tissue or the osseointegration process (e.g., cigarette smoking, poor oral hygiene, uncontrolled diabetes, oro-facial radiotherapy, steroid therapy, infections in the neighboring bone).
Special caution is advised in patients who receive bisphosphonate therapy.
In general, implant placement and prosthetic design must accommodate individual patient conditions. In case of bruxism or unfavorable jaw relationships reappraisal of the treatment option may be considered.
Because of the small size of the devices, care must be taken that they are not swallowed or aspirated by the patient.
Products in damaged packages should not be used on the patient.

Users

Dental implant surgery requires appropriate and adequate training.

It is strongly recommended that clinicians, new as well as experienced implant users, always go through special training before undertaking a new treatment method.
Close cooperation between surgeon, restorative dentist and dental laboratory technician is essential for a successful implant treatment.

Handling Instructions

Modifications of abutments could be performed using copious water irrigation.
Extra-oral modification of abutment is recommended.

Clinical Procedure:

Multi Unit Angled Abutment, Multi Unit Titanium Abutment

1. Select appropriate abutment and check occlusal clearance.
2. Connect and tighten the abutment. It is recommended to verify the final abutment seating using radiographic imaging.
3. Tighten the abutment using Abutment Screw with Driver Torque 1,2 and Adjustable Torque Wrench prosthetic.

Multi Unit Straight

1. Select appropriate abutment and check occlusal clearance.
2. Connect and tighten the abutment. It is recommended to verify the final abutment seating using radiographic imaging.
3. Tighten the abutment using Multi Unit Torque Driver and Adjustable Torque Wrench prosthetic.

Caution: Care should be taken when trying to insert the screw. It is important that it is correctly placed. Never exceed recommended maximum tightening torque for the abutment screw. Overtightening of abutment may lead to a screw fracture.

Note: Use the appropriate torque values for the abutments. Multi Unit Abutments torque values; Standard 30 Ncm, Mini 20 Ncm. Multi Unit Titanium Abutment torque value; 30 Ncm.

Materials

All Multi Unit Straight / Angled Abutments and Abutment Screws: Grade 5 Titanium.
All Multi Unit Titanium and Abutment Screw: Grade 5 Titanium.
Multi Unit Transfer Coping: Grade 5 Titanium.
Multi Unit Castable Abutment: POM C- Delrin

Cleaning and sterilization instructions

Multi Unit Straight/Angled Abutments and Multi Unit Titanium Abutments are delivered non-sterile for single use and must be autoclave sterilization at 121˚C- 20 min prior to use.
Warning: Use of non-sterile device may lead to infection of tissues or infectious diseases.

Caution: Multi Unit Straight/Angled Abutment and Multi Unit Titanium Abutment are a single-use products that must not be reprocessed. Reprocessing could cause loss of mechanical, chemical and / or biological characteristics. Re-use could cause cross contamination.
Warning: The Abutment System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of Abutment System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Storage and handling

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 device characteristics leading to failure.

Disposal

Disposal of the device shall follow local regulations and environmental requirements, taking different contamination levels into account.

CE 1984	Notified body number		Do not re-use
REF	Reference number		Consult electronic instructions for use
LOT	Lot number	NON STERILE	Sterile (121˚C- 20 min.)
	Production date		Manufacturer Name/ Manufacturer Address
EC REP	Authorized representative in the European Community	MD	Medical Device

Manufacturer: SOLVO UK IMPLANTS CO. LTD.
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Date of update: 20 October 2022

SOLVO UK
DENTAL IMPLANT

Equator Abutment

Instructions for use

Important: Please read.

Description

A premanufactured dental implant abutment to be directly connected to an endosseous dental implant intended for use as an aid in prosthetic rehabilitation.
Equator Abutments are made of Grade 5 Titanium.
Equator Abutments are available for use with the SOLVO UK Implant Systems treatment concept with guided surgery only.

Disclaimer of liability

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SOLVO Implant disclaims any liability, express or implied, and shall have no responsibility for any direct, indirect, punitive or other damages, arising out of or in connection with any errors in professional judgment or practice in the use of SOLVO Implant products. The user is also obliged to study the latest developments in regard to this SOLVO Implant product and its applications regularly. In cases of doubt, the user has to contact SOLVO Implant.
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Intended use

Dental implant abutments are intended to be used with overdentures or partial dentures, retained in whole or in part by endosseous implants in the mandible or maxilla.

The abutments in combination with two-stage endosseous implants are used as the foundation for anchoring tooth replacements in either jaw.
Equator Abutments are intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.

Indications

Equator Abutments are pre-manufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation.

Contraindications

It is contraindicated to use abutments in:
- Patients who are medically unfit for an oral surgical procedure.
- Patients in whom adequate sizes, numbers or desirable positions of implants are not reachable to achieve safe support of functional or eventually parafunctional loads.
- Patients who are allergic or hypersensitive to commercially or Titanium.

Cautions

Pre-operative hard tissue or soft tissue deficits may yield a compromised esthetic result or unfavorable implant angulations.
To secure the long-term treatment outcome it is advised to provide comprehensive regular patient follow up after implant treatment and to inform about appropriate oral hygiene.
All instruments and tooling used in surgery must be maintained in good condition and care must be taken that instrumentation does not damage implants or other components.
Special attention has to be given to patients who have local or systemic factors that could interfere with the healing process of either bone or soft tissue or the osseointegration process (e.g., cigarette smoking, poor oral hygiene, uncontrolled diabetes, oro-facial radiotherapy, steroid therapy, infections in the neighboring bone).
Special caution is advised in patients who receive bisphosphonate therapy.
In general, implant placement and prosthetic design must accommodate individual patient conditions. In case of bruxism or unfavorable jaw relationships reappraisal of the treatment option may be considered.
Because of the small size of the devices, care must be taken that they are not swallowed or aspirated by the patient.
Products in damaged packages should not be used on the patient.

Users

Dental implant surgery requires appropriate and adequate training.

It is strongly recommended that clinicians, new as well as experienced implant users, always go through special training before undertaking a new treatment method.
Close cooperation between surgeon, restorative dentist and dental laboratory technician is essential for a successful implant treatment.

Handling Instructions

Modifications of abutments could be performed using copious water irrigation.
Extra-oral modification of abutment is recommended.

Clinical Procedure

1. Select appropriate abutment.
2. Connect and tighten the abutment. It is recommended to verify the final abutment seating using radiographic imaging.
3. Tighten the abutment using Driver Torque 1,2 and Adjustable Torque Wrench prosthetic.

Caution: Use of higher torque values than recommended could cause a fracture of the abutment.

Note: Use the appropriate torque values for the abutments.
Torque values; Standard 25 Ncm, Mini 20 Ncm, Ultra Mini 15 Ncm.

Materials

All Equator Abutments: Grade 5 Titanium.
Equator Metal Cap: Grade 5 Titanium.
Equator Cap: Polyamide 6.6.
Retentive Ring: Polyamide 6.6.

Cleaning and sterilization instructions

Equator Abutments are delivered non-sterile for single use and must be autoclave sterilization at 121˚C-20 min prior to use.
Warning: Use of non-sterile device may lead to infection of tissues or infectious diseases.
Caution: Equator Abutments are a single-use products that must not be reprocessed. Reprocessing could cause loss of mechanical, chemical and / or biological characteristics. Re-use could cause cross contamination.
Warning: The Abutment System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of Abutment System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Storage and handling

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 device characteristics leading to failure.

Disposal

Disposal of the device shall follow local regulations and environmental requirements, taking different contamination levels into account.

CE 1984	Notified body number		Do not re-use
REF	Reference number	eIFU Indicator	Consult electronic instructions for use
LOT	Lot number	NON STERILE	Sterile (121˚C- 20 min.)
	Production date		Manufacturer Name/ Manufacturer Address
EC REP	Authorized representative in the European Community	MD	Medical Device

Manufacturer: SOLVO UK IMPLANTS CO. LTD.
Address: 60 Millmead Business Center Mill Mead Road N17 9QU LONDON/ENGLAND
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Web: www.solvoimplants.com

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Address: Schiffgraben 41, 30175 Hannover, Germany

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Date of update: 20 October 2022

SOLVO UK
DENTAL IMPLANT

UCLA Abutment

Instructions for use

Important: Please read.

Description

A premanufactured dental implant abutment to be directly connected to an endosseous dental implant intended for use as an aid in prosthetic rehabilitation.
UCLA Abutments are made of POM C-Delrin material.
UCLA Abutments are available for use with the SOLVO UK Implant Systems treatment concept with guided surgery only.

Disclaimer of liability

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Please note that some products detailed in this Instruction for Use may not be regulatory cleared, released or licensed for sale in all markets.

Intended use

Dental implant abutments are intended to be used in the upper or lower jaw and used for supporting tooth replacements to restore chewing function.
The abutments in combination with two-stage endosseous implants are used as the foundation for anchoring tooth replacements in either jaw.
It is designed for use as a cast part.

Indications

UCLA Abutments are pre-manufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation.

Contraindications

It is contraindicated to use abutments in:
- Patients who are medically unfit for an oral surgical procedure.
- Patients in whom adequate sizes, numbers or desirable positions of implants are not reachable to achieve safe support of functional or eventually parafunctional loads.
- Patients who are allergic or hypersensitive to commercially or Titanium.

Cautions

Pre-operative hard tissue or soft tissue deficits may yield a compromised esthetic result or unfavorable implant angulations.
To secure the long-term treatment outcome it is advised to provide comprehensive regular patient follow up after implant treatment and to inform about appropriate oral hygiene.
All instruments and tooling used in surgery must be maintained in good condition and care must be taken that instrumentation does not damage implants or other components.
Special attention has to be given to patients who have local or systemic factors that could interfere with the healing process of either bone or soft tissue or the osseointegration process (e.g., cigarette smoking, poor oral hygiene, uncontrolled diabetes, oro-facial radiotherapy, steroid therapy, infections in the neighboring bone).
Special caution is advised in patients who receive bisphosphonate therapy.
In general, implant placement and prosthetic design must accommodate individual patient conditions. In case of bruxism or unfavorable jaw relationships reappraisal of the treatment option may be considered.
Because of the small size of the devices, care must be taken that they are not swallowed or aspirated by the patient.
Products in damaged packages should not be used on the patient.

Users

Dental implant surgery requires appropriate and adequate training.
It is strongly recommended that clinicians, new as well as experienced implant users, always go through special training before undertaking a new treatment method.
Close cooperation between surgeon, restorative dentist and dental laboratory technician is essential for a successful implant treatment.

Handling Instructions

Modifications of abutments could be performed using copious water irrigation.
Extra-oral modification of abutment is recommended.

Clinical Procedure:

1. Select appropriate abutment and check occlusal clearance.
2. Connect and tighten the abutment. It is recommended to verify the final abutment seating using radiographic imaging.
3. Tighten the abutment using Abutment Screw with Driver Torque 1,2 and Adjustable Torque Wrench prosthetic.

Caution: Care should be taken when trying to insert the screw. It is important that it is correctly placed. Never exceed recommended maximum tightening torque for the abutment screw. Overtightening of abutment may lead to a screw fracture.

Note: Use the appropriate torque values for the abutments. Torque values; Standard 30 Ncm, Mini 20 Ncm.

Materials

All UCLA Abutments: POM C-Delrin.
UCLA Abutment Screws: Grade 5 Titanium.

Cleaning and sterilization instructions

UCLA Abutments are delivered non-sterile for single use and must be autoclave sterilization at 121˚C- 20 min prior to use.
Warning: Use of non-sterile device may lead to infection of tissues or infectious diseases.
Caution: UCLA Abutments are a single-use products that must not be reprocessed. Reprocessing could cause loss of mechanical, chemical and / or biological characteristics. Re-use could cause cross contamination.
Warning: The Abutment System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of Abutment System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Storage and handling

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 device characteristics leading to failure.

Disposal

Disposal of the device shall follow local regulations and environmental requirements, taking different contamination levels into account.

CE 1984	Notified body number		Do not re-use
REF	Reference number	eIFU Indicator	Consult electronic instructions for use
LOT	Lot number	NON STERILE	Sterile (121˚C- 20 min.)
	Production date		Manufacturer Name/ Manufacturer Address
EC REP	Authorized representative in the European Community	MD	Medical Device

Manufacturer: SOLVO UK IMPLANTS CO. LTD.
Address: 60 Millmead Business Center Mill Mead Road N17 9QU LONDON/ENGLAND
E-Mail: info@solvodental.com
Web: www.solvoimplants.com

EC REP
EU Authorized Representative:
MDSS GmbH
Address: Schiffgraben 41, 30175 Hannover, Germany

TF.01_2.2-2.6 / Ver. 3.0 / English
Date of update: 20 October 2022

SOLVO UK
DENTAL IMPLANT

Healing Abutment

Instructions for use

Important: Please read.

Description

A premanufactured dental implant abutment to be directly connected to an endosseous dental implant intended for use as an aid in prosthetic rehabilitation.
Healing Abutments are made of Grade 5 Titanium.
Healing Abutments are available for use with the SOLVO UK Implant Systems treatment concept with guided surgery only.

Disclaimer of liability

This product is part of an overall concept and may only be used in conjunction with the associated original products according to the instructions recommendation of SOLVO Implant. Non-recommended use of products made by third parties in conjunction with SOLVO Implant products will void any warranty or other obligation, express or implied, of SOLVO Implant.
The user of SOLVO Implant products has the duty to determine whether or not any product is suitable for the particular patient and circumstances.
SOLVO Implant disclaims any liability, express or implied, and shall have no responsibility for any direct, indirect, punitive or other damages, arising out of or in connection with any errors in professional judgment or practice in the use of SOLVO Implant products. The user is also obliged to study the latest developments in regard to this SOLVO Implant product and its applications regularly. In cases of doubt, the user has to contact SOLVO Implant.
Since the utilization of this product is under the control of the user, it is his/her responsibility. SOLVO Implant does not assume any liability whatsoever for damage arising thereof.
Please note that some products detailed in this Instruction for Use may not be regulatory cleared, released or licensed for sale in all markets.

Intended use

Dental implant abutments are used to support dental restorations. Healing Abutments are placed in connection with the dental implant. Throughout the GH level of the abutment, the gingiva is supported so that the gum develops in proper form during healing.

Indications

Healing Abutments are pre-manufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation.

Contraindications

It is contraindicated to use abutments in:
- Patients who are medically unfit for an oral surgical procedure.
- Patients in whom adequate sizes, numbers or desirable positions of implants are not reachable to achieve safe support of functional or eventually parafunctional loads.
- Patients who are allergic or hypersensitive to commercially or Titanium.

Cautions

Pre-operative hard tissue or soft tissue deficits may yield a compromised esthetic result or unfavorable implant angulations.
To secure the long-term treatment outcome it is advised to provide comprehensive regular patient follow up after implant treatment and to inform about appropriate oral hygiene.
All instruments and tooling used in surgery must be maintained in good condition and care must be taken that instrumentation does not damage implants or other components.
Special attention has to be given to patients who have local or systemic factors that could interfere with the healing process of either bone or soft tissue or the osseointegration process (e.g., cigarette smoking, poor oral hygiene, uncontrolled diabetes, oro-facial radiotherapy, steroid therapy, infections in the neighboring bone).
Special caution is advised in patients who receive bisphosphonate therapy.
In general, implant placement and prosthetic design must accommodate individual patient conditions. In case of bruxism or unfavorable jaw relationships reappraisal of the treatment option may be considered.
Because of the small size of the devices, care must be taken that they are not swallowed or aspirated by the patient.
Products in damaged packages should not be used on the patient.

Users

Dental implant surgery requires appropriate and adequate training.

It is strongly recommended that clinicians, new as well as experienced implant users, always go through special training before undertaking a new treatment method.
Close cooperation between surgeon, restorative dentist and dental laboratory technician is essential for a successful implant treatment.

Handling Instructions

Modifications of abutments could be performed using copious water irrigation.
Extra-oral modification of abutment is recommended.

Clinical Procedure

1. Select appropriate abutment and check occlusal clearance.
2. Connect and tighten the abutment. It is recommended to verify the final abutment seating using radiographic imaging.
3. Tighten the abutment using Driver Torque 1,2 and Adjustable Torque Wrench prosthetic.

Caution: Never exceed recommended maximum tightening torque for the abutment. Overtightening of the abutment may lead to fracture.

Note: Use the appropriate torque values for the abutments.
Torque values; 5 - 8 Ncm

Materials

All Healing Abutments: Grade 5 Titanium.

Cleaning and sterilization instructions

Healing Abutments are delivered non-sterile for single use and must be autoclave sterilization at 121˚C- 20 min prior to use.
Warning: Use of non-sterile device may lead to infection of tissues or infectious diseases.
Caution: Healing Abutment is single use products that must not be reprocessed. Reprocessing could cause loss of mechanical, chemical and / or biological characteristics. Re-use could cause cross contamination.
Warning: The Abutment System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment.
The safety of Abutment System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Storage and handling

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 device characteristics leading to failure.

Disposal

Disposal of the device shall follow local regulations and environmental requirements, taking different contamination levels into account.

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EC REP
EU Authorized Representative:
MDSS GmbH
Address: Schiffgraben 41, 30175 Hannover, Germany

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Date of update: 20 October 2022

SOLVO UK
DENTAL IMPLANT

Threaded Abutment

Instructions for use

Important: Please read.

Description

A premanufactured dental implant abutment to be directly connected to an endosseous dental implant intended for use as an aid in prosthetic rehabilitation.
Straight Abutment and Angled Abutment are made of Grade 5 Titanium.
Straight Abutment and Angled Abutment are available for use with the SOLVO UK Implant Systems treatment concept with guided surgery only.

Disclaimer of liability

This product is part of an overall concept and may only be used in conjunction with the associated original products according to the instructions recommendation of SOLVO Implant. Non-recommended use of products made by third parties in conjunction with SOLVO Implant products will void any warranty or other obligation, express or implied, of SOLVO Implant.
The user of SOLVO Implant products has the duty to determine whether or not any product is suitable for the particular patient and circumstances.
SOLVO Implant disclaims any liability, express or implied, and shall have no responsibility for any direct, indirect, punitive or other damages, arising out of or in connection with any errors in professional judgment or practice in the use of SOLVO Implant products. The user is also obliged to study the latest developments in regard to this SOLVO Implant product and its applications regularly. In cases of doubt, the user has to contact SOLVO Implant.
Since the utilization of this product is under the control of the user, it is his/her responsibility. SOLVO Implant does not assume any liability whatsoever for damage arising thereof.
Please note that some products detailed in this Instruction for Use may not be regulatory cleared, released or licensed for sale in all markets.

Intended Use

Dental implant abutments are intended to be used in the upper or lower jaw and used for supporting tooth replacements to restore chewing function.

The abutments in combination with two-stage endosseous implants are used as the foundation for anchoring tooth replacements in either jaw. Restorations range from replacing one single tooth to fixed partial dentures using cement-retained supra-constructions.

Indications

Straight Abutments and Angled Abutments are pre-manufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation.

Contraindications

It is contraindicated to use abutments in:
- Patients who are medically unfit for an oral surgical procedure.
- Patients in whom adequate sizes, numbers or desirable positions of implants are not reachable to achieve safe support of functional or eventually parafunctional loads.
- Patients who are allergic or hypersensitive to commercially or Titanium.

Cautions

Pre-operative hard tissue or soft tissue deficits may yield a compromised esthetic result or unfavorable implant angulations.
To secure the long-term treatment outcome it is advised to provide comprehensive regular patient follow up after implant treatment and to inform about appropriate oral hygiene.
All instruments and tooling used in surgery must be maintained in good condition and care must be taken that instrumentation does not damage implants or other components.
Special attention has to be given to patients who have local or systemic factors that could interfere with the healing process of either bone or soft tissue or the osseointegration process (e.g., cigarette smoking, poor oral hygiene, uncontrolled diabetes, oro-facial radiotherapy, steroid therapy, infections in the neighboring bone).
Special caution is advised in patients who receive bisphosphonate therapy.
In general, implant placement and prosthetic design must accommodate individual patient conditions. In case of bruxism or unfavorable jaw relationships reappraisal of the treatment option may be considered.
Because of the small size of the devices, care must be taken that they are not swallowed or aspirated by the patient.
Products in damaged packages should not be used on the patient.

Users

Dental implant surgery requires appropriate and adequate training.

It is strongly recommended that clinicians, new as well as experienced implant users, always go through special training before undertaking a new treatment method.
Close cooperation between surgeon, restorative dentist and dental laboratory technician is essential for a successful implant treatment.

Handling Instructions

Modifications of abutments could be performed using copious water irrigation.
Extra-oral modification of abutment is recommended.

Clinical Procedure:

1. Select appropriate abutment and check occlusal clearance.
2. Connect and tighten the abutment. It is recommended to verify the final abutment seating using radiographic imaging.
3. Tighten the abutment using Abutment Screw with Driver Torque 1,2 and Adjustable Torque Wrench prosthetic.

Caution: Care should be taken when trying to insert the screw. It is important that it is correctly placed. Never exceed recommended maximum tightening torque for the abutment screw. Overtightening of abutment may lead to a screw fracture.

Note: Use the appropriate torque values for the abutments. Torque values; Standard 30 Ncm, Mini 20 Ncm, Ultra Mini 15 Ncm.

Materials

Threaded Abutments and Abutment Screws: Grade 5 Titanium.
Threaded Metal Cap: Grade 5 Titanium.
Threaded Cap: Polyamide 6.6.
Retentive Ring: Polyamide 6.6.

Cleaning and sterilization instructions

Straight Abutments and Angled Abutments are delivered non-sterile for single use and must be autoclave sterilization at 121° C- 20 min prior to use.
Warning: Use of non-sterile device may lead to infection of tissues or infectious diseases.
Caution: Straight Abutment and Angled Abutment are single-use products that must not be reprocessed. Reprocessing could cause loss of mechanical, chemical and / or biological characteristics. Re-use could cause cross contamination.
Warning: The Abutment System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment.
The safety of Abutment System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Storage and handling

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 device characteristics leading to failure.

Disposal

Disposal of the device shall follow local regulations and environmental requirements, taking different contamination levels into account.

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