Please return the items sterilised, labelled and shrink-wrapped to:
medentis medical GmbH, Walporzheimer Str. 48-52, 53474 Bad Neuenahr-Ahrweiler, Germany

PRACTICE AND CONTACT DETAILS

Customer number: _____ **Name of practice / laboratory:** _____

Stamp:

BASIC DATA for COMPLAINTS or EXCHANGES

(Label, if present, is sufficient. In the case of ICX-Liquid implants, a refund can only be made if the packaging (with lot number) is also sent or an anonymous copy of the patient 's implant passport is submitted)

REF No.	LOT No.	Number	Product is sent back to medentis	
			Yes	no

Note: If you do not provide any information on the treatment results and the effect on the patient (see page 3), we will assume that no harm has been done to the patient.

DATES (DD/MM/YYYY)

Complaint/Exchange: _ _ _ _ _ _ _ _

Implantation: _ _ _ _ _ _ _ _ ☐ n.a.

Exposure: _ _ _ _ _ _ _ _ ☐ n.a.

Temporary restoration: _ _ _ _ _ _ _ _ ☐ n.a.

☐ Immediate implantation

If something occurs at the same time as implantation:
☐ before ☐ during / after surgical intervention

Explant: _ _ _ _ _ _ _ _ ☐ n.a.

Final care: _ _ _ _ _ _ _ _ ☐ n.a.

PATIENT DETAILS (HISTORY)

Risk Factors:

☐ Decreased blood clotting ☐ chemotherapy
☐ radiotherapy ☐ tobacco abuse ☐ alcohol abuse
☐ Insufficient bone supply ☐ Poor oral hygiene ☐ bruxism
☐ Periodontitis/gingivitis/ peri-implantitis ☐ Allergy:_____
☐ Inadequate soft tissue coverage ☐ Other:_____
☐ Systemic disorder / metabolic disease

bone quality: ☐ Type I ☐ Type II/III ☐ Type IV

COMPLAINT: IMPLANT

Patient complained of: ☐ Pains ☐ sensory disturbance ☐ swelling ☐ n.a.

Implant loss due to:

☐ fracture
☐ deformation
☐ Excessive clamping with secondary part
☐ Insufficient osseointegration (during the healing phase)
☐ Insufficient primary stability (detected during surgery)
☐ Loss of osseointegration (after healing phase)
☐ Excessive clamping with insertion tool
☐ External trauma (accident) / surgical trauma caused by treatment on neighboring teeth
☐ Fractured components that cannot be removed from the implant
If applicable: used drills _____

Possible cause(s):

☐ peri-implantitis ☐fistula formation
☐ osteomyelitis ☐ implant mobility ☐ Mechanical overload
☐ nerve injury ☐ Allergic reaction ☐ bone fracture
☐ perforation of the sinus membrane ☐ soft tissue recession ☐ bone necrosis
☐ Excessive bone loss ☐ connective tissue healing ☐ cement residue
☐ hyperplasia ☐ bleeding ☐ Fenestration / dehiscence defect

Augmentation: ☐ preoperative at the ☐ same time as implantation Material: _____
☐ No assessment possible

Insertion torque (Ncm): _____ **Region : _____**

Other reason: ☐ Foreign particles / surface contamination

☐ Damaged thread ☐ Inadequate clamping with insertion instrument

For additional description (possible reasons/causes) see section "Miscellaneous, Description", page 3

PROSTHETIC RESTORATION

☐ Crown ☐ Bridge ☐ bar

partial denture: ☐ U J ☐ L J

full denture: ☐ U J ☐ L J

Other, please describe:_____

COMPLAINT: CONSTRUCTION / CONNECTING SCREW / HEALING CAP / SCREW CAP

Reason: ☐ deformation ☐ wear

☐ relaxation d. connecting screw ☐ fracture ☐ allergic reaction

☐ splintering of zircon ☐ detachment d. Zirconium cap from Ti base

☐ external trauma (accident) / surgical trauma caused by treatment on neighboring teeth

☐ insufficient or ☐ excessive clamping with: ☐ implant ☐ instruments / accessories

Possible cause(s): ☐ mechanical overload ☐ use of abrasive toothpaste

☐ divergences greater than 40° ☐ no assessment possible

torque (Ncm): _____

For additional description (possible reasons/causes) see section "Miscellaneous, Description", page 3

COMPLAINT: DRILL

Reason:

☐ faulty drilling behavior ☐ fracture ☐ deformation

☐ allergic reaction ☐ corrosion ☐ defective coating

☐ insufficient or ☐ excessive clamping with: ☐ angle / hand piece ☐ drill extension / ratchet adapter

For additional description (possible reasons/causes) see section "Miscellaneous, Description", page 3

COMPLAINT: INSTRUMENTS

Reason: ☐ fracture ☐ deformation

☐ allergic reaction ☐ corrosion ☐ wear

☐ insufficient or ☐ excessive clamping with: ☐ implant ☐ angle / hand piece

☐ abutment ☐ drill extension / ratchet adapter

Approximate number of implants/fixed abutments placed with this instrument: _____

For additional description (possible reasons/causes) see section "Miscellaneous, Description", page 3

COMPLAINT: ACCESSORIES

Reason: ☐ fracture ☐ deformation

☐ allergic reaction ☐ corrosion ☐ wear

☐ retention loss ☐ lamella fracture ☐ discoloration

☐ insufficient or ☐ excessive clamping with: ☐ implant ☐ angle / hand piece

☐ construction ☐ drill / instrument

For additional description (possible reasons/causes) see section "Miscellaneous, Description", page 3

DETAILS of an EXCHANGE	
Delivery:	☐Wrong product included / missing product ☐ Delayed delivery
Packaging:	☐ Damaged packaging (hole / tear etc.) ☐ Broken vial ☐ Interrupted / opened sealing seam ☐ Incorrect or no product included / missing product when at least 2 should be included ☐ Aluminum cap cannot be opened (ICX-Liquid)
Labelling:	☐ Incorrect/missing/misleading information provided in human-readable form ☐ Wrong / missing / misleading information provided in symbols ☐ Incorrect / missing / ambiguous information provided in the QR code or in the data matrix ☐ Wrong / missing / ambiguous information on patient sticker ☐ No patient label included ☐ Wrong / missing marking on the product
Instructions for use:	☐ Wrong / missing / misleading information ☐ Electronic instructions for use not accessible
Miscellaneous:	☐ Expiry date expired ☐ Loss of sterility ☐ Exchange for another size / variant ☐ Implant loss (e.g. in the case of abutments connected to the implant)

IMPACT of the EVIDENCE on the PATIENT and the THERAPY SUCCESS

☐ 1. No or minimal risk to the patient and/or the success of the therapy. Inconvenience or temporary discomfort.
No further surgically invasive intervention required

☐ 2. Moderate risk for the patient, but higher risk for the success of the treatment. May require further invasive surgical procedures (longer rehabilitation).

☐ **3.** Serious/catastrophic risk to the patient (in accordance with Article 2, 65-66, Regulation (EU) 2017/745 – MDR), resulting in permanent impairment or life-threatening injury, including death, and/or posing a serious threat to public health.

See the "Other, Description" section at the bottom of this page for additional description. If you complain about several products, you can also describe the (different) effects here, stating the corresponding number (1-3, as defined above) and assignment to the respective product.

EFFECT of the EVIDENCE on the USER

☐ None

Or describe, see the following section "Miscellaneous, Description"

OTHER, DESCRIPTION

PRODUCT RETURN INFORMATION

Products intended for return, if they have been in contact with a patient and are potentially contaminated, must be cleaned, disinfected and sterilized prior to return (refer to the relevant instructions for use or the R1 reprocessing instructions for cleaning, disinfection and sterilization details). The products must be packaged in suitable sterilization packaging and have an appropriate indicator confirming the sterilization that has been carried out. ISO 12891-1 provides more detailed information about the removal, handling and return of surgical implants.

After completion of the complaint processing, medentis archives the complaint goods with the associated documents, unless otherwise specified by the customer. In the case of complaint goods from third parties, medentis assumes that consent has been obtained.

CONFIRMATION and SIGNATURE

With my signature, I confirm the correctness of the information given above regarding the complaint or exchange.

Place and date	**Signature of the (dentist) doctor**

Reference number(s) (assigned by medentis):