Instructions for use for custom-made implants

1. General

These instructions for use apply to custom-made implants planned and manufactured by AQ Solutions GmbH.

The application of the products requires special knowledge and skills in endoprosthetic implantology. Improper procedures during implantation of the prostheses can lead to failures, implant malfunction, injury to the patient, bone loss or unsatisfactory aesthetic results. These products may therefore only be used by surgeons trained in the implant system.

AQ Solutions GmbH offers training and/or consultations on the technical application of its products for users and provides detailed information on the implants as well as on the preoperative planning and the surgical technique. Application advice on our products is given orally, in writing, by means of electronic media and/or by demonstration. This advice corresponds to the current state of science and technology as known at the time the product is placed on the market. This does not release the user from their own obligation to test the product for its suitability for the intended purposes, indications, and procedures.

Products from AQ Solutions GmbH are only supplied to doctors and specialist staff or on their behalf. The handling and implantation of the product are the responsibility of the user. Any liability for damage caused in this way is excluded.

2. Product description and intended use

The implants developed by AQ Solutions GmbH are specially designed for the treatment of complex defect situations, bone and joint anomalies of all kinds and for defects from the field of tumour surgery.

These custom-made implants are manufactured according to the current state of the art and are intended as individual products for a named patient for whom, from a doctor's point of view, treatment with a standard implant appears to be insufficient.

The implants are manufactured to written prescription and according to the instructions of the treating physician and can only be used for this patient.

⚠ **Caution:**

Custom-made products must only be used for the patient it was manufactured for.

Each custom-made implant is provided with a unique identification number (REF or serial number). Both the identification number and the other identification features are given on the labels enclosed with the respective implant. The identification number is also listed in the declaration of conformity and in all other related documents to ensure unique identifiability. The identification number of the custom-made implant must be documented in the patient files and also in the implant card that is given to the patient after the operation.

With the aim of restoring physiological joint geometry, AQ Solutions GmbH usually designs and manufactures the implants on the basis of CT data or other imaging techniques. With the optional use of 3D visualisation software, AQ Solutions GmbH aligns the treatment proposal with the surgeon, as the basis for manufacture of the custom-made product. Manufacturing is carried out exclusively on the basis of written approval by the attending physician of the submitted planning documentation.

AQ Solutions GmbH will notify the attending physician in writing about potential limitations and risks of the custom-made product; this forms part of the planning documentation. The implantation is ultimately the responsibility of the doctor.

For the treatment of acetabular defects, AQ Solutions manufactures the 3D Hemipelvis Replacement. This is used for acetabular reconstruction of larger bone defects, such as in the case of repeated revisions or tumour diseases. Depending on the indication, the prosthesis can be fixed by means of contact of the textured implant to the vital bone, individual tabs, an iliac peg, or other augments for additional stabilisation as well as by means of metal defect filling.

To treat femoral defects, AQ Solutions manufactures the CTX 3D Hip stem. This is an individual hip endoprosthesis for cementless fixation. Fixation is achieved diaphyseally or metaphyseally, depending on the indication.

In addition to the above-mentioned custom-made implants, AQ Solutions GmbH will design and manufacture other custom-made products on the basis of special design features especially for individual patients on written order of the attending physician and in accordance with his documented approval.
All special features that are not taken into account in these instructions for use will be communicated to the attending physician in the accompanying planning documents.

3. Sterility, packaging, storage

All implant components are supplied individually in sterile protective packaging. Keep the implant in the original unopened packaging until use. When removing sterile implant components, ensure that the protective packaging consisting of cardboard and peel films is unopened and undamaged. Damage can compromise the sterility of the implant. Therefore, if the seal is broken or the cardboard or the peel films are damaged, it must be assumed that the contents are non-sterile! Appropriate measures should be taken to ensure that the implant does not come into contact with objects or substances that could damage its surface.

⚠ **Caution:**

Implant components labelled 'sterile' are only sterile if the packaging is undamaged.
Visually check the implant and where appropriate the coating for any damaged areas before insertion. Do not insert implants or implant components that are damaged. Protective caps or similar devices that serve to protect sensitive areas of the implant should only be removed immediately before use. The implant must not be mechanically processed, altered or modified in any other way.
Any reprocessing of non-implanted components whose packaging has been opened or whose sterile date has expired may only be performed by the manufacturer, since individual validated processes must be passed again. Sterile implant components have been sterilised with a gamma radiation dose of at least 25 kGy.

The correct removal, handling and/or return of revised implants for scientific evaluation must be performed in accordance with ISO 12891-1. The general instructions of the ISO 8828 standard for the care and handling of orthopaedic implants must be observed.

For purchased devices, the manufacturer-specific information (handling, sterilisation, compatibility, etc.) must be observed.

4. Surgical planning and implantation

The implantation of custom-made products from AQ Solutions GmbH may only be carried out on the basis of the planning documents and surgical technique individually prepared for this purpose. Any deviation from the instructions and specifications listed there can negatively impact the accuracy of fit of the implant.

Note:

AQ Solutions GmbH expressly states that the implantation of the custom-made products manufactured on the basis of patient-specific CT and/or X-ray images, must take place as immediately as possible to ensure the accuracy of fit. If this is not observed, the suitability of the custom-made product can no longer be guaranteed owing to a possible change in the patient's individual situation. Any deviation from this requirement is the sole responsibility of the attending physician. Liability on the part of AQ Solutions GmbH is excluded in this case.

For the implantation of custom-made implants, only the instruments provided by AQ Solutions GmbH are to be used.

For the preparation of the host bone and adjustment, repositioning and implantation of the custom-made implants, AQ Solutions GmbH will also provide suitable custom instruments if required, matching the dimensions of the implants. These are manufactured taking into account the condition of the bone present and must be discarded after use. To ensure optimal primary fixation as a prerequisite for ensuring long-lasting stability of the implant, the following points must be observed:

Ensure that sufficient bone structure/wall thickness is maintained when preparing the implant bed
- Sufficient cleaning of the implant bed prior to implantation
- When implanting the implant, take care to avoid bone fissures and/or damage to the implant

For systems that are composed of several individual components, the following must be ensured:
- Clean, dry surfaces for taper connections
- Firm coupling of the tapers through the use of inserting and impacting instruments
- Avoid damaging the components during coupling
- Avoid bone and/or tissue residues between functional surfaces (e.g. tapers, holes, joint surfaces).
- Locking screws are used for screwable components (e.g. securing of the iliac peg)

Note:

The sliding and bearing surfaces and tapers of implants must be protected in particular from damage by surgical instruments or bone cement particles. Their safe long-term function is only guaranteed in an intact state and they should be protected by surgical drapes during the implantation.

5. Indications

Custom-made implants are manufactured individually for patients which are not a suitable candidate for a standard procedure from a medical point of view.

5.1 Indications for 3D Hemipelvis Replacement

- Revisions with acetabular defects of type IIIa or larger according to Paprosky
- Reconstruction of acetabular bone defects where the remaining supportive vital bone only allows for individual design of the prosthesis
- Acetabular defects due to:
  - Tumour resections in the acetabular area
  - Congenital hip dysplasia

5.2 Indications for CTX 3D Hip Stem

- Femora with anatomical anomalies for where treatment with a standard implant does not appear promising
- Femora with severe deformities, e.g. due to:
  - Corrective osteotomies
  - Post-traumatic events
  - Dysplasia
  - Abnormal dimensions in rheumatoid arthritis
  - Coxa vara/valga
  - High hip dysplasia

5.3 Indications for Cones

Indications depend on the judgement of the attending physician and the individual defect situation of the patient.

The custom-made cones are indicated in cases of femoral or tibial metaphyseal bone defects limiting the support of the knee endoprosthesis by the femoral or tibial bone.

5.4 Indications for other custom-made products

Indications depend on the judgement of the attending physician and the individual defect situation of the patient.

Note:

The indication for cementless implantation is only given if the bone quality is sufficient. Especially for patients with a cement intolerance, cementless implantation offers an adequate alternative. If a cementless restoration is contraindicated, a cemented restoration must be used.

6. Contraindications

The use of individual implants is contraindicated in the following cases:

- Acute or chronic, local or systemic infection, persistent infection
- Insufficient bone quality or insufficient bone conditions, endangering stable fixation of the implant
- Allergies to implant components
- Pregnancy or breastfeeding
- Non-compliance
- Severe immunosuppression
- Epilepsy or other circumstances that can lead to accidents with an increased risk of fracture

The assessment of a patient's general surgical ability for implantation of an individual implant is the responsibility of the attending physician.

7. Possible undesirable side effects

The expected lifespan of an implant may be impaired in very large and/or overweight persons. Patients with incomplete bone growth may experience premature loosening of the implant. Poor fitting/fixing of the implant or its use despite contraindication, may lead to premature failure due to loosening, fracture or abrasion.

Typical undesirable side effects may include:

- Loosening or change of the implants' position of and implant wear
- Implant dislocation or loosening and fracture of components
- Infection
- Impingement
- Change in limb length
- Heterotopic ossification
- Hypersensitivity to alloy components
- Periprosthetic fractures
- Chronic pain
- Pulmonary embolism and venous thrombosis
- Nerve damage, wound healing disorder and haematoma
- Cardiovascular disorders
- Restricted joint function and mobility
- Restricted joint load and joint pain
- Changes in bone tissue (atrophy, necrosis)

8. Patient information

The patient must be informed about any residual risks, undesirable side effects, the intended use of the implant and potentially damaging behaviour. The following points should be considered:

- The patient must comply with the degree of movement prescribed by the doctor in the explanatory consultation.
- The patient must perform the physiotherapy prescribed by the doctor.
- Sporting activities are only possible to a limited extent and following consultation and individual risk assessment by the attending physician.
- Both excessively high body weight and falling accidents can have a negative effect on the lifetime of the implant.
- The patient must not lift or carry heavy loads.
- Examinations using magnetic resonance tomography (MRT) for diagnosis or postoperative control can lead to interactions with the implant.

The patient must be informed that any combination with cups or asymmetrical cup inlays may lead to a limitation of the range of motion (ROM). The patient must be informed about the cases in which the attending physician is to be contacted.

9. Implant materials

The materials of the custom-made products vary depending on the implant design and/or defect situation.

The following materials are examples of those used in the implants:

- Pure titanium as per ISO 5832-2
- Titanium alloy (TiAl6V4) as per ISO 5832-3
- CoCrMo alloy as per ISO 5832-4 or ISO 5832-12
- UHMWPE - Ultra-high molecular weight polyethylene as per ISO 5834-1, -2

Coatings:

- Titanium niobium (TiNb)
- Hydroxyapatite (HA)
- Titanium niobium nitride (TiNbN)

The custom-made products are used either without cement or with bone cement (PMMA), depending on the indication. All implant materials used are indicated on the respective label.

10. Postoperative follow-up

Patients with a custom-made implant require continuous post-operative monitoring by the surgeon or a competent colleague. If there is an unforeseen premature loosening of the implant, weakening of the material or similar signs of an impending complication, promising remedial measures can then be taken in time. The chances of success of any necessary revision surgery are considerably improved by early detection, especially if the conditions of the bone bordering the implant have not yet significantly been deteriorated.

The patient should be instructed to report any changes associated with their operated joint to the surgeon or attending physician without delay. Regular clinical follow-up is recommended. If this is not possible, a control X-ray should be submitted to the surgeon or supervising specialist at least once a year for evaluation.

AQ Solutions GmbH supplies suitable instruments for revision interventions. Please observe the specific instructions in our user information and surgical techniques. If desired, our product specialists will be happy to support you in revision surgery. If you have any questions about revision procedures, please contact the implant manufacturer.

Caution:

Strong magnetic or electromagnetic fields, as occur during MRI examinations, can have a negative influence on implant behaviour. For up-to-date safety information, contact the implant manufacturer.

11. Compatibility

Compatibility of products is only guaranteed in connection with products approved for combination by AQ Solutions GmbH and its own CE-marked products.

In general, AQ Solutions GmbH cannot check the compatibility of its custom-made implants with the implanted devices of other manufacturer. For the 3D Hemipelvis Replacement, only the iliac peg with locking screw and the cancellous bone screws supplied by AQ Solutions GmbH may be used. For all other custom-made implants, the attending physician will be informed of the combination options approved by AQ Solutions GmbH. AQ Solutions GmbH will be happy to answer any questions regarding its products. When making enquiries, please have the article numbers (REF) or serial numbers of the relevant products ready.

12. Disposal

Explanted custom implants must be disposed of correctly in accordance with the applicable laws and directives. In the case of non-implanted custom products, it must be ensured that they are not used for a patient other than the named patient for whom they were made. This can be ensured by correct disposal by the clinic or return of the products to AQ Solutions GmbH.

13. Explanation of the label symbols

	Caution		Consult instructions for use or consult electronic instructions for use
	Do not re-use	REF	Catalogue number
	Date of manufacture (year-month-day)	SN	Serial number
	Use-by date(year-month-day)	LOT	Batch code
	Do not resterilize		Manufacturer
	Non-sterile	STERILE R	Sterilized using irradiation
	Keep dry		Keep away from sunlight
	Do not use if package is damaged and consult instructions for use	12 14	Taper
	Double sterile barrier system	MD	Medical device
QTY	Quantity	L | R	Side
cementless	Cementless		

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M-93090225.22