EcoFit® 2M

tripolar system

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Location: Moldova

implantcast

SURGICAL TECHNIQUE

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Nota Bene: The author of this technique has outlined the procedure for the uncomplicated surgical scenario. Ultimately however it is the operating surgeon who is best placed to assess and address the individual needs of each patient.

PREOPERATIVE PLANNING

Preoperative planning and precise surgical techniques are mandatory for optimal results. The instructions and the procedure given in the surgical technique to the system must be adhered to. Familiarity with the recommended surgical technique and its careful application is essential to achieve the best possible outcome.
Before surgery a surgical planning with regard to the dimensions of the prosthetic model and the positioning of the implant components in the bone has to be carried out by the surgeon.

For this purpose, x-ray templates are available:
Digital templates: Digital templates are included in the data base of the common planning systems. For missing templates, please contact the provider of the planning software and request for these templates.
Radiographic templates: Alternatively radiographic templates are available in various scale factors, which can be obtained from your local representative.

figures A: EcoFit® 2M cup
cementless and cemented in A/P view

figures B: EcoFit® 2M cup
cementless and cemented in M/L view

For more information, please refer to the instructions for use „EcoFit® 2M hip system“ (09300065GB) and this surgical technique from p.24.

DESIGN CHARACTERISTICS

Fig. left:
2M implacross® E head
(with Vitamin E)

Fig. right:
EcoFit® 2M head
(UHMWPE)

Highly polished articulating surface of the EcoFit® 2M cups

The EcoFit® 2M head made of implacross® E (crosslinked polyethylene with vitamin E) or UHMW-PE is snapped on the regular head. This enables the combined movement between the head with the inner surface of the EcoFit® 2M head on the one hand and between the outer surface of the EcoFit® 2M head and the EcoFit® 2M cup on the other hand. This design reduces the risk of dislocation. The inner surfaces of the EcoFit® 2M acetabular cups are highly polished.
The EcoFit® 2M cups are available in cementless and cemented versions. Cementless cups are available in outer diameters from 42 to 64mm, cemented cups in outer diameters from 44 to 64mm. Due to the tribological properties all cups are made of implavit®, CoCrMo-casting alloy. To increase the surface of the cemented treatment the cemented cups have grooves and notches. The cementless cups are coated with implaFix® coating made of pure titanium and HA to allow PressFit fixation and bony ingrowth.

outer surface of the cemented cup

outer surface of the cementless cup

SYSTEM OVERVIEW




2M implacross® E head or EcoFit® 2M head	EcoFit® 2M cup cementless	EcoFit® 2M cup cemented
22/38mm	38/42mm	38/44mm
22/40mm	40/44mm	40/46mm
28/42mm	42/46mm	42/48mm
28/44mm	44/48mm	44/50mm
28/46mm	46/50mm	46/52mm
32/48mm	48/52mm	48/54mm
32/50mm	50/54mm	50/56mm
32/52mm	52/56mm	52/58mm
32/54mm	54/58mm	54/60mm
32/56mm	56/60mm	56/62mm
32/58mm	58/62mm	58/64mm
32/58mm	58/64mm	---

The EcoFit® 2M heads made of implacross® E or UHMWPE are available in 11 sizes. They can be combined with the cementless and the cemented EcoFit® 2M cups as shown in the table above. Small diameters of 42 and 44mm (cementless) or 44 and 46mm (cemented) are used in combination with 22mm heads made of CoCrMo alloy, for bigger diameters either the 28 and 32mm heads made of CoCrMo, titanium or ceramic may be used.

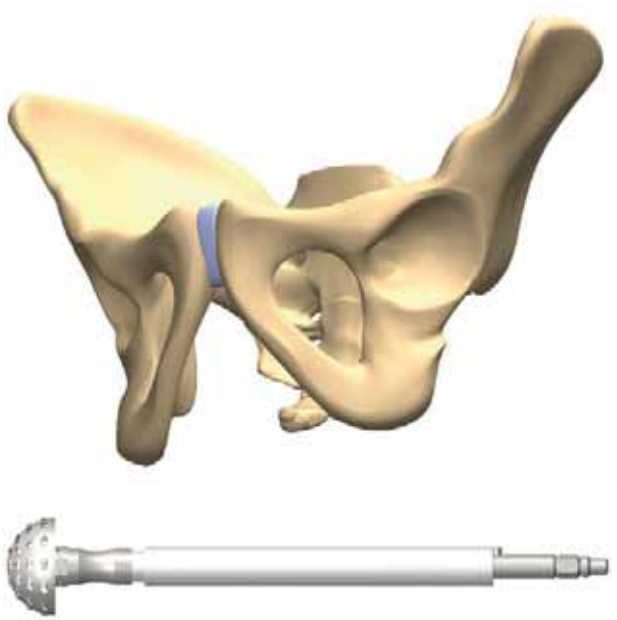


Figure 1

Preparation of the acetabulum

Please expose the hip joint completely. Resect the articular capsule and the labrum acetabulare. Dissect the bony rim of the acetabulum, if possible, completely.

Remove the osteophytes and the connective tissue of the fossa acetabuli. In order to rebuild normal anatomical proportions, the acetabulum should be medialised to the extent to which you are able to reconstruct the preoperatively chosen centre of rotation.

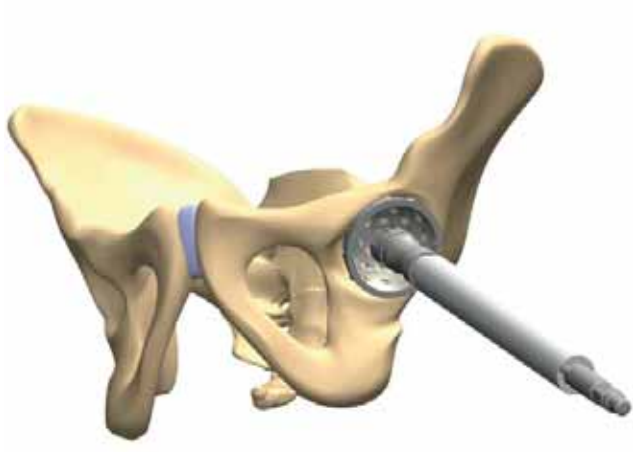


Figure 2

To prepare the acetabular bone, reamers of external diameters in increments of 2mm are available (Fig. 1).
Align the reamer anatomically, in abduction of about 45° and anteversion of 10 - 20°. By using the reamer the acetabulum is prepared until bleeding subchondral bone is reached (Fig. 2).

If a cementless cup is used, the last reamer should have the same outer diameter as the cup. For cemented cups the last reamer should be 2mm bigger than the cup.

Please note that the posterior and anterior acetabular rim serve for sizing and therefore should be preserved accordingly.

Sizing

The appropriate trial shell has to be assembled onto the shell impactor (Fig. 3a). Using the trial shells, the size of the prepared implant bed is checked (Fig. 3b).

The slots of the trial shells serve for the determination of the bone contact between the respective trial shell and the prepared acetabulum (Fig. 3c).

Strike the trial shell with the help of the shell impactor into the reamed acetabulum. The impacted trial cup should remain stable in the acetabulum.

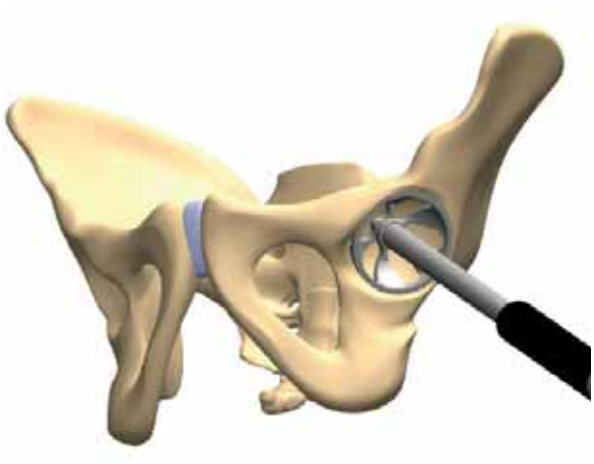


Figure 3b

Figure 3a

cup impactor optionally orange or black

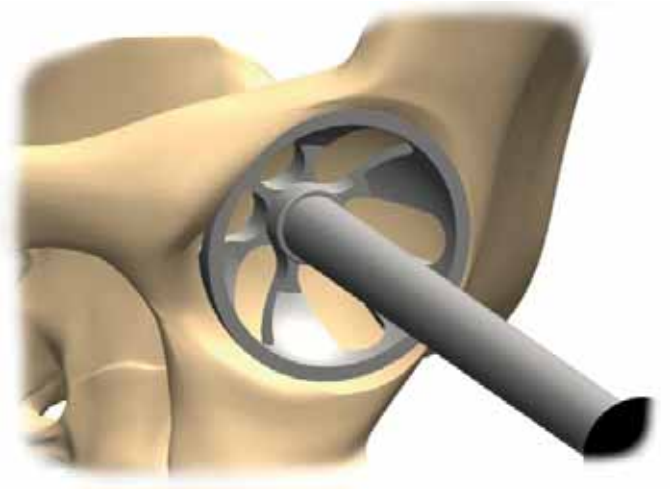


Figure 3c

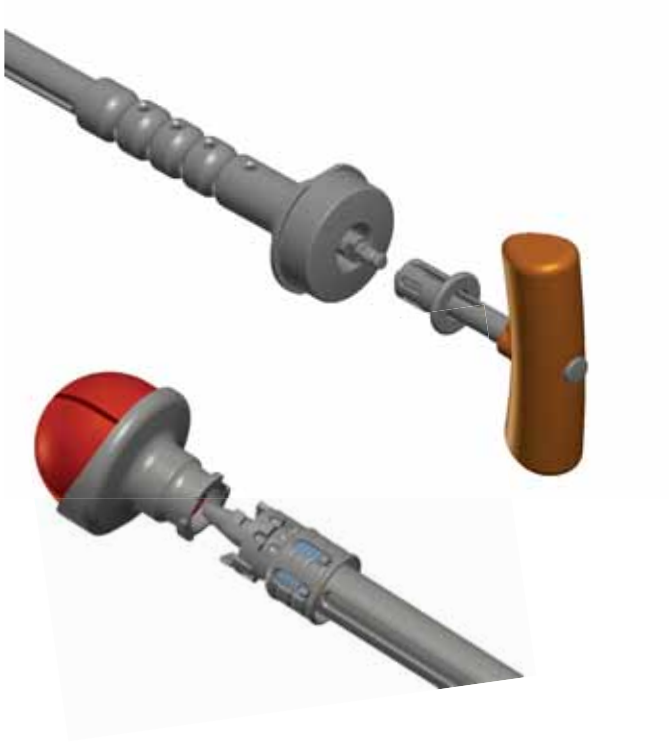


Figure 4a

Using of cup impactor straight

Assemble the ic T-handle Zimmer Jakobs on the cup impactor straight. Afterwards connect the adapter for EcoFit® 2M cup impactor straight with the cup impactor (Fig. 4a). Put the selected EcoFit® 2M cup on the adapter. Via right hand rotation of the ic T-handle the cup is getting fixed by spreading the adapter (Fig. 4b). Remove the ic T-handle for impacting the cup.

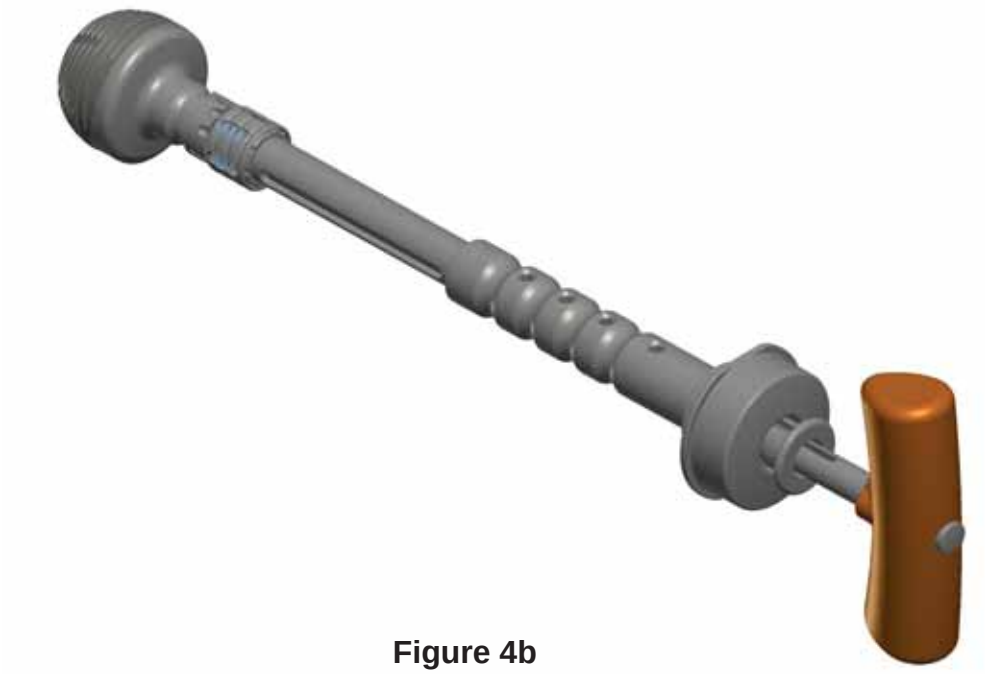


Figure 4b

Usage of cup impactor curved

Assemble the ic T-handle on the ic-adapter hexagon ball 6mm. Afterwards connect the adapter for EcoFit® 2M cup impactor curved with the impactor by extraction of the jacket. Put the selected EcoFit® 2M cup on the adapter (Fig. 5).
Via right-hand rotation of the ic T-handle the cup is getting fixed by spreading the adapter.

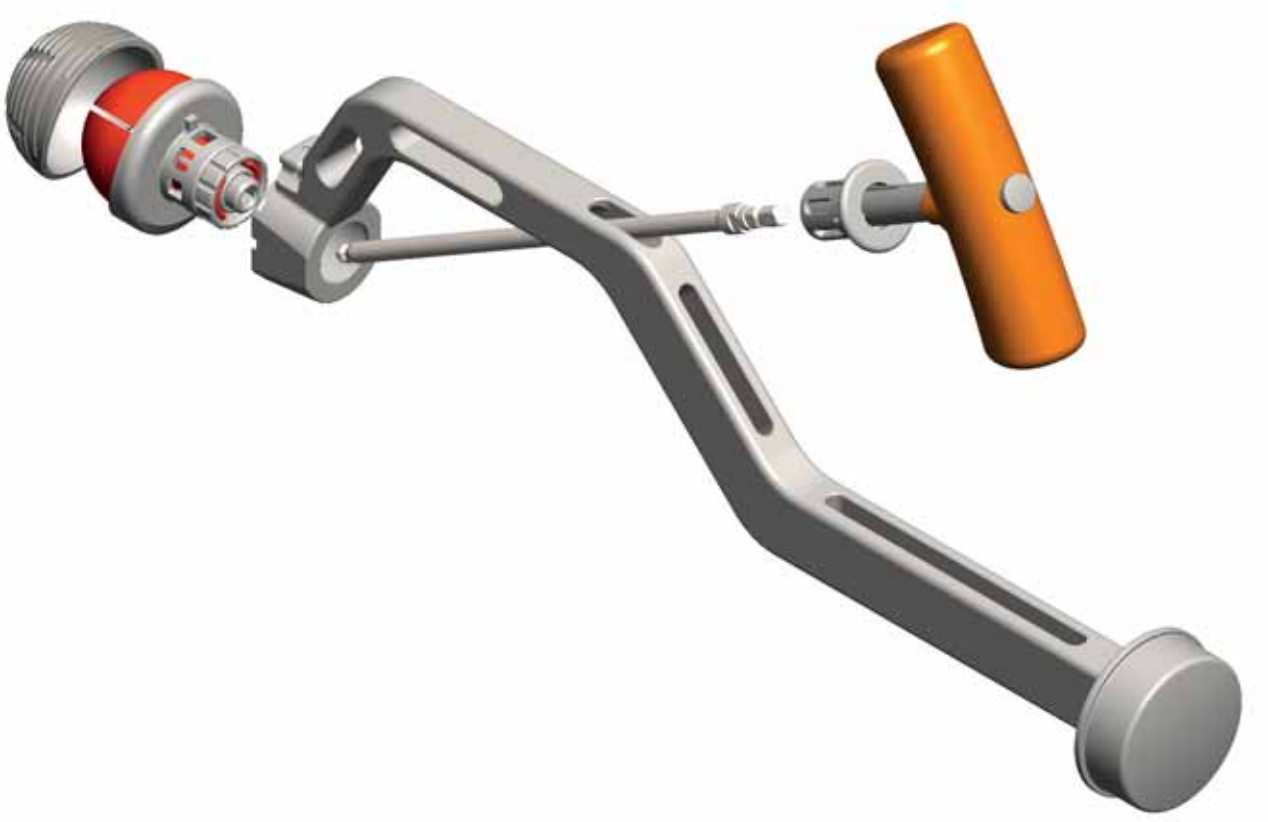


Figure 5

Figure 6a

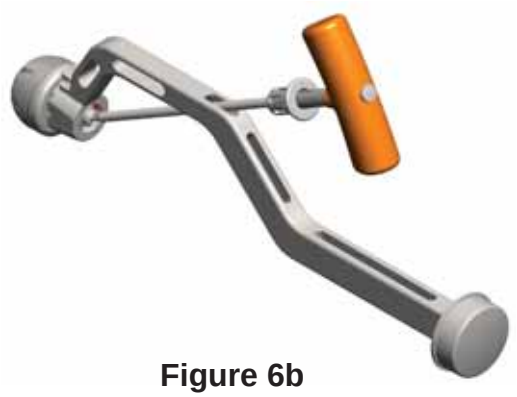


Figure 6b

Figure 6c

Insertion of the cup

The chosen EcoFit® 2M cup is combined with the cup impactor straight (Fig. 6a) or the curved (Fig. 6b) and inserted in the prepared acetabulum. Exactly aligned the EcoFit® 2M cup should rest at an angle of abduction of 45° and an anteversion of 10-20°. The lasermarking stands on the highest point of the cup edge surface. Impact the cup with the straight or the curved impactor (Fig. 7a and 7b).

cementless implantation

The chosen size of the EcoFit® 2M cup should have the same diameter as the previously used reamer. The HA-coating produces the pressFit of the cup.

The stability of the implant fit (PressFit) and the implant-to-bone contact can be adjusted by moving the impactor at the end of the handle. In doing so the whole pelvic should move without changing the position of the cup in the acetabulum.

cemented implantation

The chosen size of the EcoFit® 2M cup should be 2mm smaller as the previously used reamer. In this way a circumferential cementle mantle of 1mm is reached.

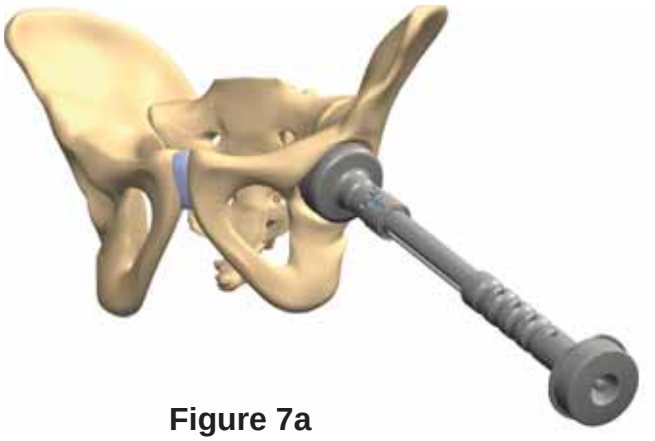


Figure 7a

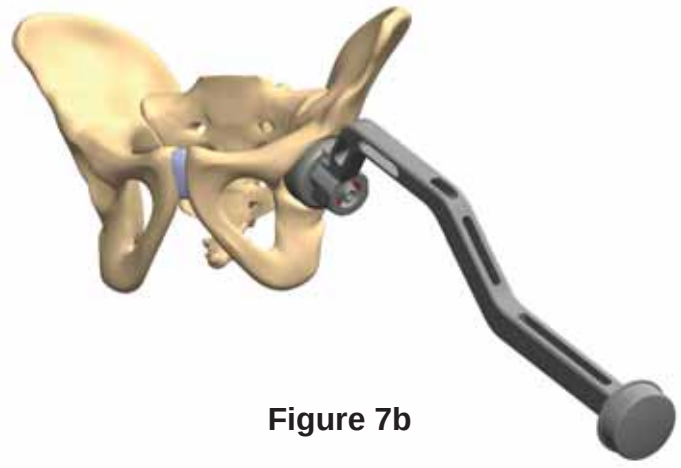


Figure 7b

Loosen the selected impactor with the ic T-handle (Fig. 8a and 8b).

In the case of cemented implantation the pushing during the hardening of the bone cement occurs with the aid of the shell impactor and the 2M trial head which can be connected due to a M10x1 thread (Fig. 9).

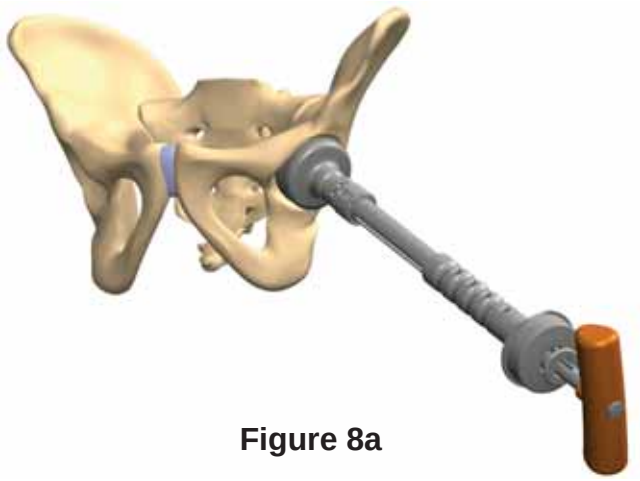


Figure 8a

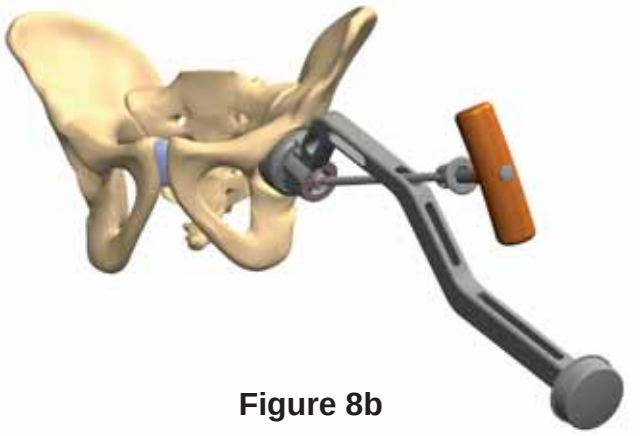


Figure 8b

Trial reduction

When the EcoFit® 2M cup is fixed firmly in the desired position (Fig. 10), the 2M trial head of the appropriated size may be inserted for the trial reduction (Fig. 11). The size of the trial component corresponds to the inner diameter of the implanted cup.

Combine the trial head with the stem of the hip system and perform a trial reduction.

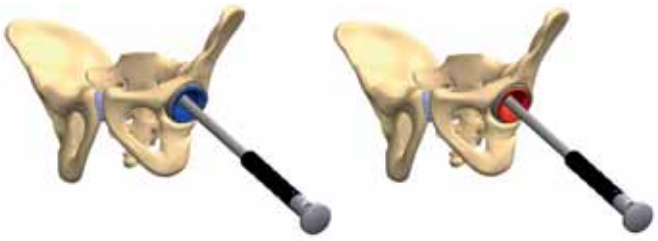


Figure 9

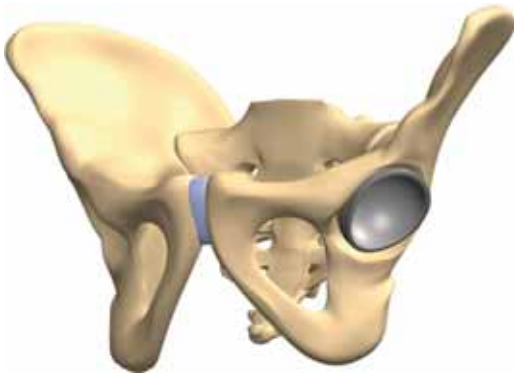


Figure 10

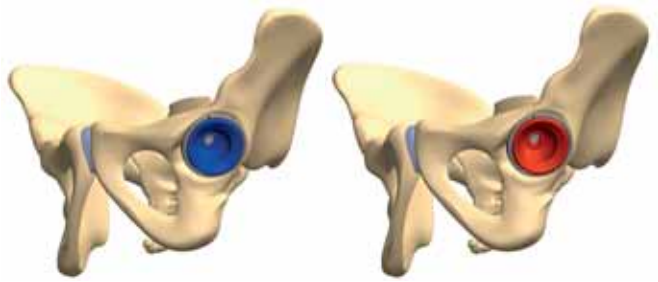


Figure 11

Fgure 11a

Combination of the components

Combine the 2M head of the respective size with the desired ic-head (Fig. 11a). For this use the assembling tool (Fig. 11b). ic-head and 2M head will be combined by turning the thread of the assembling tool.

With the head impactor and some slightly strokes the combined heads can be fixed on the taper of the femoral stem (Fig. 11c).

Figure 11b

Figure 11c

Final reduction

Combine the implanted hip stem with the selected head and set the joint component.

Perform a final stability check and check the range of motion (Fig. 12 and 13).

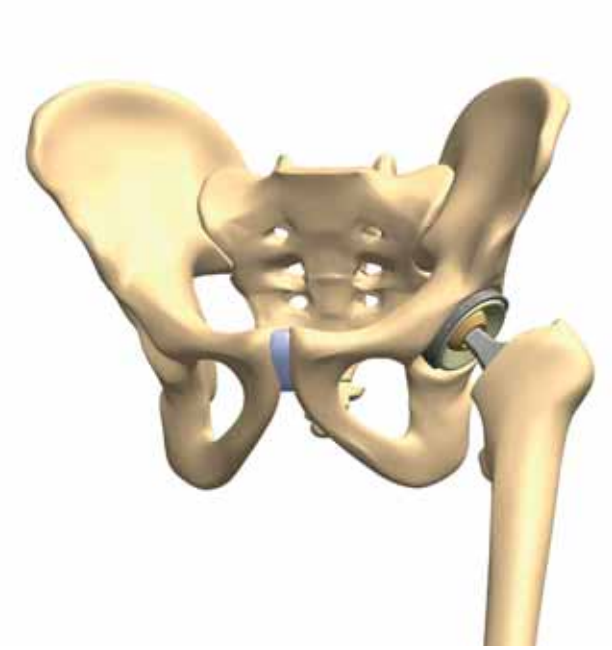


Figure 12

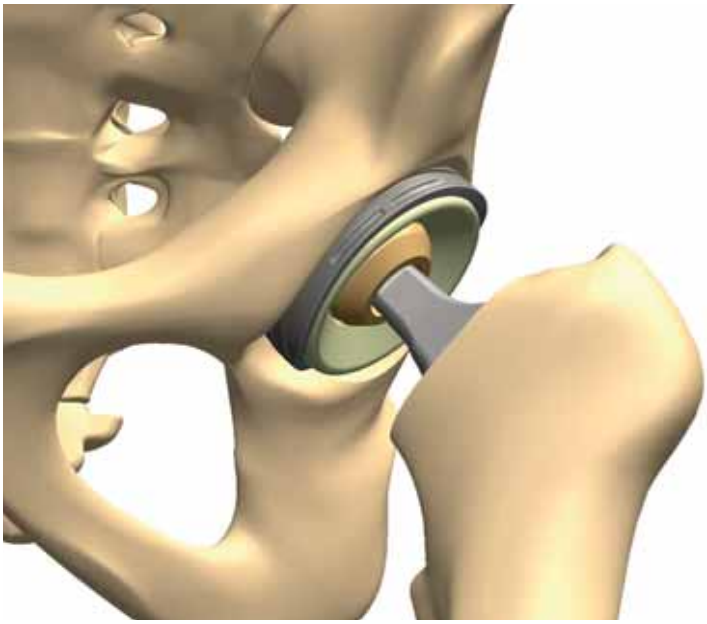
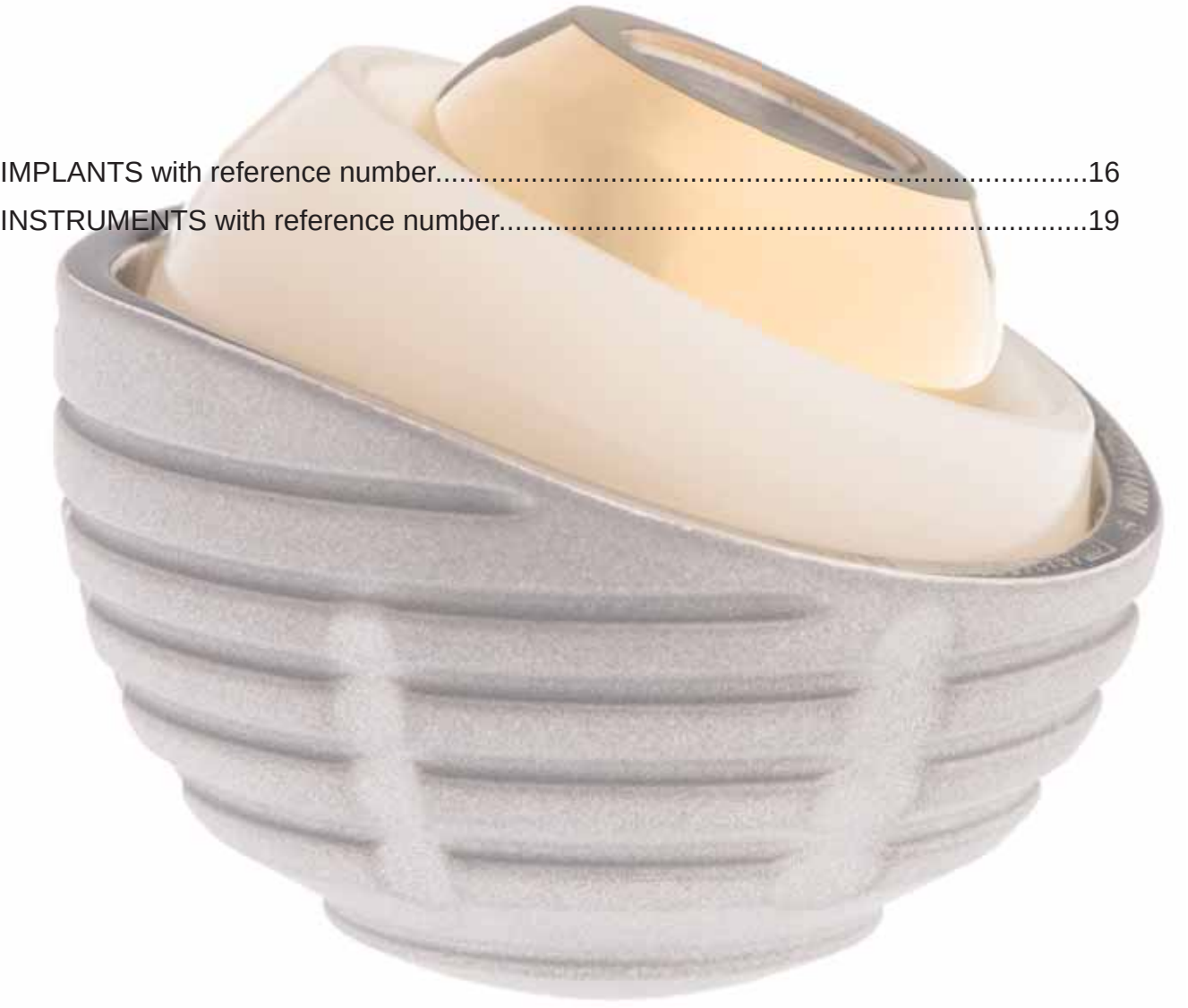


Figure 13

EcoFit® 2M
PRODUCT-INFORMATION



IMPLANTS with reference number.....16
INSTRUMENTS with reference number.....19

IMPLANTS

EcoFit® 2M cup, cementless

implavit®, CoCrMo acc. to ISO 5832-4 with
implaFix® cpTi-coating and HA-coating acc. to 13779-2

REF	Size (inner-Ø/outer-Ø)
0220-1042	38/42mm
0220-1044	40/44mm
0220-1046	42/46mm
0220-1048	44/48mm
0220-1050	46/50mm
0220-1052	48/52mm
0220-1054	50/54mm
0220-1056	52/56mm
0220-1058	54/58mm
0220-1060	56/60mm
0220-1062	58/62mm
0220-1064	58/64mm

EcoFit® 2M cup, cemented

implavit®, CoCrMo acc. to ISO 5832-4

REF	Size (inner-Ø/outer-Ø)
0220-1144	38/44mm
0220-1146	40/46mm
0220-1148	42/48mm
0220-1150	44/50mm
0220-1152	46/52mm
0220-1154	48/54mm
0220-1156	50/56mm
0220-1158	52/58mm
0220-1160	54/60mm
0220-1162	56/62mm
0220-1164	58/64mm

EcoFit® 2M cup TiN, cemented

implavit®, CoCrMo acc. to ISO 5832-4 with TiN-coating

REF	Size (inner-Ø/outer-Ø)
0220-1144N	38/44mm
0220-1146N	40/46mm
0220-1148N	42/48mm
0220-1150N	44/50mm
0220-1152N	46/52mm
0220-1154N	48/54mm
0220-1156N	50/56mm
0220-1158N	52/58mm
0220-1160N	54/60mm
0220-1162N	56/62mm
0220-1164N	58/64mm

IMPLANTS

2M implacross® E head

implacross® E, crosslinked UHMWPE with vitamin E

REF	Size (inner-Ø/outer-Ø)
2905-2238	22/38mm
2905-2240	22/40mm
2905-2842	28/42mm
2905-2844	28/44mm
2905-2846	28/46mm
2905-2848	28/48mm*
2905-2850	28/50mm*
2905-2852	28/52mm*
2905-2854	28/54mm*
2905-2856	28/56mm*
2905-2858	28/58mm*
2905-3248	32/48mm
2905-3250	32/50mm
2905-3252	32/52mm
2905-3254	32/54mm
2905-3256	32/56mm
2905-3258	32/58mm

EcoFit® 2M head

UHMWPE acc. to ISO 5834-2

REF	Size (inner-Ø/outer-Ø)
2906-2238	22/38mm
2906-2240	22/40mm
2906-2842	28/42mm
2906-2844	28/44mm
2906-2846	28/46mm
2906-2848	28/48mm*
2906-2850	28/50mm*
2906-2852	28/52mm*
2906-2854	28/54mm*
2906-2856	28/56mm*
2906-2858	28/58mm*
2906-3248	32/48mm
2906-3250	32/50mm
2906-3252	32/52mm
2906-3254	32/54mm
2906-3256	32/56mm
2906-3258	32/58mm

*** Implants and corresponding 2M trial heads are only available on request.**

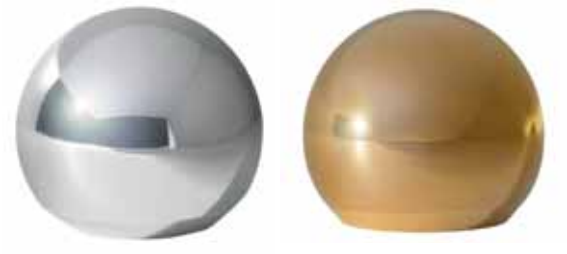
IMPLANTS

BIOLOX® forte **ic-head** **BIOLOX® delta**

Al_2O_3 acc. to ISO 6474-1

Al_2O_3 and ZrO_2 acc. to ISO 6474-2

REF	Size	REF
2587-2800	28mm, S	2586-2800
2587-2805	28mm, M	2586-2805
2587-2810	28mm, L	2586-2810
2587-3200	32mm, S	2586-3200
2587-3205	32mm, M	2586-3205
2587-3210	32mm, L	2586-3210
-	32mm, XL	2586-3215



CoCrMo **ic-head** **Titanium**

implavit® CoCrMo acc. to ISO 5832-12

implatan® $TiAl_6V_4$ acc. to ISO 5832-3 with TiN-coating

REF	Size	REF
2312-2200	22mm, S	-
2312-2205	22mm, M	-
2312-2210	22mm, L	-
2387-2800	28mm, S	2787-2800
2387-2805	28mm, M	2787-2805
2387-2810	28mm, L	2787-2810
2387-2815	28mm, XL	2787-2815
2387-3200	32mm, S	2787-3200
2387-3205	32mm, M	2787-3205
2387-3210	32mm, L	2787-3210
2387-3215	32mm, XL	2787-3215

figure ic-head CoCrMo with TiN-coating
22mm neck length L (large)

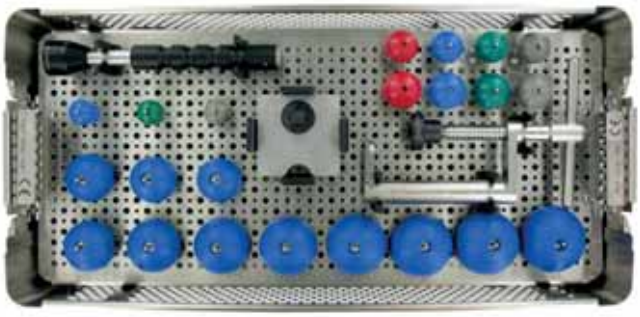
CoCrMo **ic-head**

implavit® CoCrMo acc. to ISO 5832-12 with TiN-coating

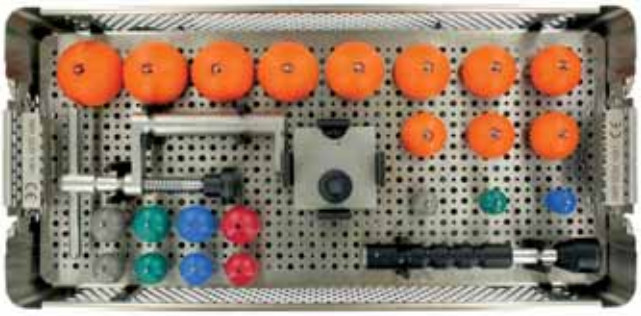
REF	Size
2322-2200	22mm, S
2322-2205	22mm, M
2322-2210	22mm, L

INSTRUMENTS

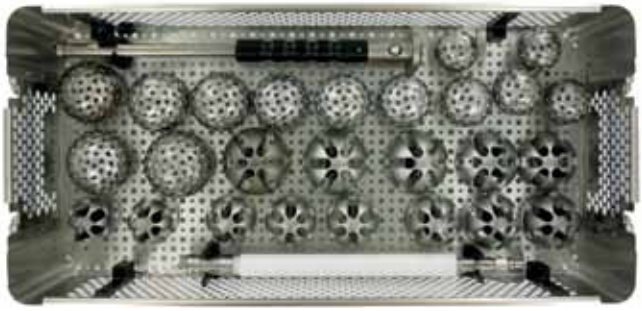
0220-1081
EcoFit® 2M container I (top)
(version with blue trial heads)



0220-1081
EcoFit® 2M container I (top)
(version with orange trial heads)



0220-1081
EcoFit® 2M container I (bottom)



0220-1082
EcoFit® 2M container II

0220-1083
EcoFit® 2M Container III
Sales will be discontinued, limited availability

Instruments are delivered non-sterile. The relevant information on reprocessing must be observed.

INSTRUMENTS

CONTAINER 0220-1081

acetabulum reamer low profile

2950-3042 / 2960-3042	Ø 42mm
2950-3044 / 2960-3044	Ø 44mm
2950-3046 / 2960-3046	Ø 46mm
2950-3048 / 2960-3048	Ø 48mm
2950-3050 / 2960-3050	Ø 50mm
2950-3052 / 2960-3052	Ø 52mm
2950-3054 / 2960-3054	Ø 54mm
2950-3056 / 2960-3056	Ø 56mm
2950-3058 / 2960-3058	Ø 58mm
2950-3060 / 2960-3060	Ø 60mm
2950-3062 / 2960-3062	Ø 62mm
2950-3064 / 2960-3064	Ø 64mm
2950-3066 / 2960-3066	Ø 66mm

handle for acetabulum reamer
2950-2010

trial shell

2950-2342	Ø 42mm
2950-2344	Ø 44mm
2950-2346	Ø 46mm
2950-2348	Ø 48mm
2950-2350	Ø 50mm
2950-2352	Ø 52mm
2950-2354	Ø 54mm
2950-2356	Ø 56mm
2950-2358	Ø 58mm
2950-2360	Ø 60mm
2950-2362	Ø 62mm
2950-2364	Ø 64mm
2950-2366	Ø 66mm

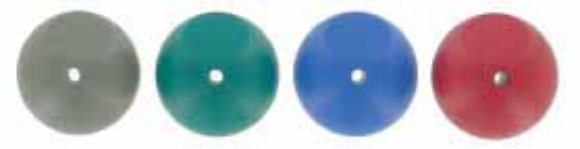
shell impactor
0282-0020

shell impactor (optional)
0282-0030

INSTRUMENTS

trial head snap taper 12/14

7962-2200 / 7965-2200	Ø 22mm short
7962-2205 / 7965-2205	Ø 22mm medium
7962-2210 / 7965-2210	Ø 22mm long
7962-2800 / 7965-2800	Ø 28mm short
7962-2805 / 7965-2805	Ø 28mm medium
7962-2810 / 7965-2810	Ø 28mm long
7962-2815 / 7965-2815	Ø 28mm x-long
7962-3200 / 7965-3200	Ø 32mm short
7962-3205 / 7965-3205	Ø 32mm medium
7962-3210 / 7965-3210	Ø 32mm long
7962-3215 / 7965-3215	Ø 32mm x-long



femoral head impactor
2950-0039

ic head assembling tool
2900-2000

2M trial head

2950-2238	22/38mm
2950-2240	22/40mm
2950-2842	28/42mm
2950-2844	28/44mm
2950-2846	28/46mm
2950-3248	32/48mm
2950-3250	32/50mm
2950-3252	32/52mm
2950-3254	32/54mm
2950-3256	32/56mm
2950-3258	32/58mm

either blue version or orange version is available - there is no difference in function, only the colors differ

CONTAINER 0220-1082

EcoFit® 2M cup impactor straight
0220-1800

adapter for EcoFit® 2M cup impactor straight

0220-1838	38mm
0220-1840	40mm
0220-1842	42mm
0220-1844	44mm
0220-1846	46mm
0220-1848	48mm
0220-1850	50mm
0220-1852	52mm
0220-1854	54mm
0220-1856	56mm
0220-1858	58mm

ic T-handle Zimmer-Jakobs
4223-0023

INSTRUMENTS

CONTAINER 0220-1083

EcoFit® 2M cup impactor curved
0220-1900

ic adapter with hexagonball 6mm
7512-3606

adapter for EcoFit® 2M cup impactor curved

0220-1938	38mm
0220-1940	40mm
0220-1942	42mm
0220-1944	44mm
0220-1946	46mm
0220-1948	48mm
0220-1950	50mm
0220-1952	52mm
0220-1954	54mm
0220-1956	56mm
0220-1958	58mm

ic T-handle Zimmer-Jakobs
4223-0023

PRE- / POST-OPERATIVE INSTRUCTIONS

Intended Use

The EcoFit® 2M system is a tripolar acetabular cup system (dual mobility) for total hip arthroplasty that consists of a metallic acetabular shell (EcoFit® 2M Cup) and a head made of polyethylene (EcoFit® 2M head / 2M implacross® E head) which serves as an internal bearing. The head made of polyethylene is intended for connection with a metallic or ceramic femoral head. The EcoFit® 2M Cup is intended either for a cementless or a cemented fixation.
The heads (EcoFit® 2M Head / 2M implacross® E Head) can additionally be used with a metallic insert (EcoFit® Insert / EcoFit® Insert TiN / 2M insert 15° for MUTARS® RS cup and LUMiC® TiN) in combination with press-fit acetabular cups and revision / tumor acetabular cups respectively in a modular dual mobility hip replacement.

Pre-operative Instructions

The implantation is carried out according to the established surgical technique which is available from the implantcast GmbH. A list of the associated surgical techniques is provided at the end of the instructions for use of the EcoFit® 2M hip system “09300065 EcoFit® 2M hip system“.

Further to this the surgeon should determine whether:

- All necessary components are available during surgery. An adequate number of various implant components should be available for surgery. It should be determined as to whether the implantation should be done with or without the use of bone cement.
- All instruments for the implantation are present. The insertion instruments must be adapted to the implant. The implants may only be associated with the instruments of the implantcast GmbH. Only the standardized instruments are excepted.

The surgeon must make sure that the correct sized instruments are used during surgery to prevent damage to the implants.
The instruments of the implantcast GmbH are supplied non-sterile and must be disinfected, cleaned and sterilized before use. Please refer to the cleaning statement RA_000_ISO17664 for the correct procedures. If the equipment is not treated before use, there is a risk of infection.

Post-operative Instructions

Post-operative patient care, patient instructions and warnings are of the utmost importance.
The use of an external support for a limited period, to stimulate healing is recommended.
Especially active and passive movements of the patients should be monitored.
The post-operative regime should be aimed at the prevention of overloading of the joint and stimulation of the healing process.
Regular monitoring of position and condition of the prosthetic components and the surrounding bone is recommended.

INDICATIONS / CONTRAINDICATIONS

Indications

The decision for replacement of the joint should be based on careful evaluation. The indication for this type of surgery should only be made when all other conservative or surgical alternatives are less promising.
Danger of post-operative complications can be limited by careful evaluation of the individual anatomical and load conditions, the condition of the soft tissues and the condition of the bone bed for the implants.
The provision of prostheses is generally indicated only in patients whose skeleton is fully grown.
Before intervention, preoperative examinations should be performed. The examinations depend on the patient's history.
Under consideration of these conditions the total hip replacement with the EcoFit® 2M hip system applies to the following indications:

- Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis,
- Post-traumatic osteoarthritis,
- Fractures,
- Rheumatoid arthritis.
- Hip dysplasia,

in patients with an increased risk of dislocation;

- Revision hip arthroplasty

The surgeon decides which version of prosthesis for the individual patient is used. This decision depends on several factors, such as the age and the patient's weight, bone quality, shape of the bone and deformation of the joint.

Contraindications

The longevity of an orthopaedic joint replacement device can be reduced by biological aspects, material characteristics and biomechanical factors. Patient selection and indication should be carefully monitored especially in patients who are overweight, patients with high physical activity levels and patients younger than 60 years of age.
An absolute contraindication is a known allergy to any of the implant materials used. The label on the secondary packaging of each component specifies the material used. Indication for testing, it is strongly recommended to perform an allergy test.
A further absolute contraindication is infection.
The relative contraindications include:

1. Anatomic conditions, which preclude or are not expected to maintain an adequate bony support of the implant or do not allow the implantation of a sufficiently large prosthesis.
   - Insufficient quantity and quality of bone stock, e.g. as a result of osteoporosis or osteomalacia
   - Vascular disease of the affected limb
2. Metabolic disorders that can affect a stable anchorage of the implant
3. Bone tumors in the implant fixation area
4. Neuromuscular diseases that can impair the affected limb
5. Lack of patient compliance
6. Mental or neurological conditions that affect the ability of patients to comply with medical instructions, especially during the healing phase
7. Obesity

Risk factors

The following risk factors may affect the success of joint replacement:

- Nicotine and/or drug abuse
- Alcoholism
- Muscle insufficiency
- Severe deformities, which lead to an impairment of the anchorage, the exact positioning or function of the implant
- Excessive loading of the operated joint by strong physical work and/or inappropriate sports
- Therapies that may affect bone quality

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