

PART OF THE TECHNICAL DOCUMENTATION

PRODUCT DESCRIPTION **ECOFIT® 2M SYSTEM**

PRODUCT-GROUP: PRIMARY ARTHROPLASTY,
REVISIONSARTHROPLASTY

RISK-CLASS: III

LOCATION: HIP

DATE: 30.11.2016

ECOFIT® 2M SYSTEM



FIGURE 1: ECOFIT® 2M SYSTEM

In 1976 the principle of dual mobility in hip arthroplasty was introduced by Professor Bousquet and the Medical School of Saint Etienne in France. This principle consists of a metal or ceramic femoral head which is locked onto an “inlay” made of UHMW-PE (such as the EcoFit® 2M head) which moves freely in a metallic shell. That way two points of articulation are given which ensures the dual mobility:

1. An ic- head with the PE inserts
2. The PE insert with the metal shell

In comparison to bipolar or unipolar hip arthroplasty the EcoFit® 2M system offers an increased range of motion through its tripolar composition. Additionally the dual mobility design provides higher stability because bigger head diameters can be used. This leads to a higher protection against luxations.

THE ECOFIT® 2M SYSTEM IS INTENDED FOR USE IN PATIENTS REQUIRING HIP ARTHROPLASTY DUE TO:

- NON INFLAMMATORY DEGENERATIVE JOINT DISEASE INCLUDING OSTEOARTHRITIS AND AVASCULAR NECROSIS,
- POST-TRAUMATIC OSTEOARTHRITIS,
- FRACTURES,
- RHEUMATOID ARTHRITIS.

The acetabular components of the EcoFit® 2M system are available for cementless and cemented use. The femoral heads used with the 2M implacross® E head or EcoFit® 2M head are all femoral heads by implantcast with the respective diameters of 22, 28 or 32 mm.

Indications for the EcoFit® 2M system can be primary surgeries because of arthritis, degenerative or rheumatoid arthritis, joint fractures or bone necrosis and dysplasia as well as revision surgeries that require big head arthroplasties because of high risks of dislocations.



ECOFIT® 2M ACETABULAR CUP CEMENTLESS



FIGURE 3: LEFT: ECOFIT® 2M CUP CEMENTLESS
RIGHT: ECOFIT® 2M CUP CEMENTLESS SP

The cementless acetabular cups serve as a replacement for a diseased acetabulum. It articulates with a 2M implacross® E head or EcoFit® 2M head to build a dual mobility hip arthroplasty. The cups are made of implavit®, CoCrMo-casting alloy.

The EcoFit® 2M Cup cementless provides an overhang which position can be chosen freely intraoperatively. The EcoFit® 2M cup cementless SP provides 4 spikes for rotational stability. The cementless acetabular cups are coated on the outer surface and provides a highly polished rim which builds a clean closure for the coating.

The outer side offers a triradial design while the inner side is an almost complete hemisphere with medial flattening. A cavity with a nose close to the rim of the cup offers a stable and secure coupling with an explanation instrument.

The table below shows further coating specifications.

TABLE 1: COATING SPECIFICATIONS OF ECOFIT® 2M CUP CEMENTLESS

CHARACTERISTICS	VALUE	
	cpTi (ISO 5832-2)	HA (ISO 13779-2)
COATING THICKNESS	300 ± 50 µm	60 ± 20 µm
POROSITY	30 ± 10 %	≤ 30%
AVERAGE ROUGHNES Rt	Rt = 175 +/- 50 µm	50 ± 20 µm
TENSILE STRENGTH	> 22 MPa	≥ 15 MPa
SHEAR STRENGTH	> 20 MPa	≥ 20 MPa

The EcoFit® 2M acetabular cup cementless as well as the EcoFit® 2M cup cementless SP are available in 12 outer diameters matching the inner diameters of the implacross® E head as well as the EcoFit® 2M head. The sizes of the cementless EcoFit® 2M cups are provided in the following table.

TABLE 2: SIZES OF ECOFIT® 2M CUP CEMENTLESS & ECOFIT® 2M CUP CEMENTLESS SP

* : ONLY AVAILABLE FOR ECOFIT® 2M CUP CEMENTLESS / ** : ONLY AVAILABLE FOR ECOFIT® 2M CUP CEMENTLESS SP

INNER DIAMETER [mm]	38	40	42	44	46	48	50	52	54	56	58	58*	60**
OUTER DIAMETER [mm]	42	44	46	48	50	52	54	56	58	60	62	64*	64**

ECOFIT® 2M ACETABULAR CUP CEMENTED



FIGURE 4: LEFT: ECOFIT® 2M CUP CEMENTED
RIGHT: ECOFIT® 2M CUP CEMENTED TiN

The cemented acetabular cups serve as a replacement for a diseased acetabulum. It articulates with the 2M implacross® E head resp. EcoFit® 2M head to build a dual mobility hip arthroplasty. The EcoFit® 2M acetabular cups are used with bone cement.

The cups are made of implavit®, CoCrMo-casting alloy. The outer side offers hemispheric macro geometry while the inner side is an almost complete hemisphere. Both sides provide a medial flattening. To ensure a safe fixation of the cup with the bone cement grooves have been integrated in the posterior surface (cement fixation surface). The cup has circumferential circular grooves to enhance tilt stability and cement compression and six (6) equally spaced radial grooves to provide rotational stability for cement fixation.

The acetabular cup provides an overhang which position can be chosen freely intraoperatively. A cavity close to the rim of the cup offers a stable and secure coupling with an explantation instrument.

The cementless cups are coated with implaFix® coating made of pure titanium and HA to allow press-fit fixation and bony ingrowth. The table below shows further coating specifications.

TABLE 3: COATING SPECIFICATIONS OF ECOFIT® 2M CUP CEMENTED

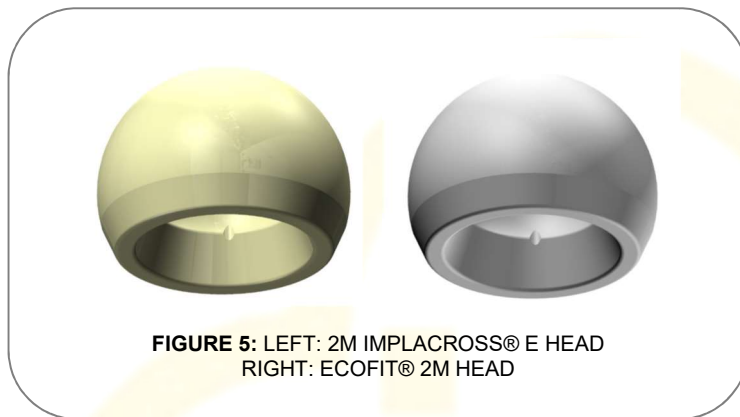
CHARACTERISTICS	VALUE
	TiN
COATING THICKNESS	5,5 ± 1,5 µm
AVERAGE ROUGHNESS Ra	< 0.05 µm
TENSILE STRENGTH	≥ 22 MPa
VDI 3824 – ROCKWELL C	HF 1-4
COATING HARDNESS	HV = 2400 ± 400

The EcoFit® 2M acetabular cup cemented is head is available in 12 outer diameters matching the inner diameters of the implacross® E head. The sizes of the EcoFit® 2M cup cemented head are provided in the following table.

TABLE 4: SIZES OF ECOFIT® 2M CUP CEMENTED

INNER DIAMETER [mm]	38	40	42	44	46	48	50	52	54	56	58
OUTER DIAMETER [mm]	44	46	48	50	52	54	56	58	60	62	64

2M IMPLACROSS® E HEAD & ECOFIT® 2M HEAD



**FIGURE 5: LEFT: 2M IMPLACROSS® E HEAD
RIGHT: ECOFIT® 2M HEAD**

The 2M implacross® E heads as well as the EcoFit® 2M heads rotate freely in the EcoFit® 2M acetabular cup.

The outer surface articulates with the EcoFit® 2M cup and the inner surface articulates with the various ic-heads.

The 2M implacross® E head and the EcoFit® 2M head are available in

various sizes matching the inner diameter of the EcoFit® 2M cup and the outer diameter of the ic-head respectively.

The heads made of implacross® E (crosslinked polyethylene with vitamin E) or UHMW-PE are snapped on the regular head. Through this combination the system allows a combined articulating of the two bearings; between an ic-head and the EcoFit® 2M head resp. 2M implacross® E head (see

FIGURE) and the outer surface of the EcoFit® 2M head resp. 2M implacross® E head and a EcoFit® 2M Cup. This design reduces the risk of subluxations while having a large range of motion.

The 2M implacross® E head and the EcoFit® 2M head are available in six (6) outer diameters matching two (2) inner diameters of the ic-heads. The sizes of the 2M implacross® E head are provided in the following table.

TABLE 5: SIZES OF 2M IMPLACROSS® E HEAD & ECOFIT® 2M HEAD

INNER DIAMETER [mm]	22		28				28 / 32				
OUTER DIAMETER [mm]	38	40	42	44	46	48	50	52	54	56	58



**FIGURE 6: COMBINATION OF THE IC-HEAD AND THE ECOFIT® 2M HEAD
RESP. 2M IMPLACROSS® E HEAD**

The 2M implacross® E heads and the EcoFit® 2M heads mate with metal shells having an outer diameter corresponding to the inner diameter of the EcoFit® 2M Acetabular Cup. The compatible 2M implacross® E heads resp. the EcoFit® 2M head and metal shells are listed in the following table.

TABLE 6: COMPATIBILITY OF ECOFIT® 2M SYSTEM

* : NOT AVAILABLE FOR ECOFIT® 2M CUP CEMENTLESS SP / ** : ONLY AVAILABLE FOR ECOFIT® 2M CUP CEMENTLESS SP

ECOFIT® 2M ACETABULAR CUP CEMENTLESS SIZE: ID/OD [mm]	ECOFIT® 2M ACETABULAR CUP CEMENTED SIZE: ID/OD [mm]	2M IMPLACROSS® E HEAD & ECOFIT® 2M HEADS SIZE: ID/OD [mm]	IC-HEADS CoCrMo (FOR EXAMPLE) Size: OD [mm]
38/42	38/44	22/38	22
40/44	40/46	22/40	22
42/46	42/48	28/42	28
44/48	44/50	28/44	28
46/50	46/52	28/46	28
48/52	48/54	28/48	28
50/54	50/56	28/50	28
52/56	52/58	28/52	28
54/58	54/60	28/54	28
56/60	56/62	28/56	28
58/62 58/64*	58/64	28/58	28
48/52	48/54	32/48	32
50/54	50/56	32/50	32
52/56	52/58	32/52	32
54/58	54/60	32/54	32
56/60	56/62	32/56	32
58/62 58/64*	58/64	32/58	32
60/64**	-	-	-