



CERTIFICAT

Prin prezentul, BC "EXIMBANK-Gruppo Veneto Banca" S.A., Filiala nr.20, BIC EXMMMD22477 confirmă faptul deținerii de către compania **"ORTOFIX" SRL** cod fiscal: **1014600000772** a următoarelor conturi curente:

Valuta	Nr. Cont	Cod IBAN
MDL	2251656584MD	MD36EX0000002251656584MD
MDL	2251656584MD2	MD75EX0000002251656584MD2
MDL	2251656584MD3	MD48EX0000002251656584MD3
EUR	2251656584EU	MD83EX20000002251656584EU
USD	2251656584US	MD05EX20000002251656584US

Certificatul este eliberat pentru a fi prezentat la cerere.

Director adjunct Filiala Nr. 20
Badan Andrei



Executor: Baran Margareta
Telefon: +373 22 301-227





AGENȚIA SERVICII PUBLICE
Departamentul înregistrare și licențiere a unităților de drept

EXTRAS
din Registrul de stat al persoanelor juridice
Nr. 519394 data 27.04.2023

Denumirea completă: **Societatea cu Răspundere Limitată "ORTOFIX"**

Denumirea prescurtată: **S.R.L. "ORTOFIX"**

Forma juridică de organizare: **Societate cu răspundere limitată,**

Numărul de identificare de stat și codul fiscal (IDNO): **1014600000772**

Data înregistrării de stat: **14.01.2014**

Modul de constituire: **nou creată.**

Sediul: **MD-2028, str. Mt. Gurie Grosu, 15/4, mun. Chișinău, Republica Moldova.**

Obiectul principal de activitate:

- 1. Comerțul cu amănuntul al articolelor medicale și ortopedice**
- 2. Alte tipuri de comerț cu ridicata**

Capitalul social: **5400 lei,**

Administrator: **BOLOCAN VASILE, IDNP 0960702546445,**
numit în funcție pe termen **nelimitat.**

Asociații:

1. **BOLOCAN GALINA, IDNP 0972811038010, cota 5400 lei, ce constituie 100%**

Beneficiar efectiv: 1. **BOLOCAN GALINA, IDNP 0972811038010, cota - 100%**

Prezentul extras este eliberat în temeiul art.34 al Legii nr.220-XVI din 19 octombrie 2007 privind înregistrarea de stat a persoanelor juridice și a întreprinzătorilor individuali și confirmă datele din Registrul de stat la data de: **27.04.2023.**

Registrator în domeniul
înregistrării de stat



Lozovanu Constantin



EB 0417321



GUVERNUL
REPUBLICII
MOLDOVA



SERVICIUL FISCAL DE STAT



CERTIFICAT

privind lipsa sau existența restanțelor față de bugetul public național

Nr.
Nº

Din
От

1

DATE DESPRE CONTRIBUABIL/ИНФОРМАЦИЯ О НАЛОГОПЛАТЕЛЬЩИКЕ

Codul fiscal/Numărul de identificare

Фискальный код/Идентификационный номер

Denumirea

Наименование

2

ATESTAREA LIPSEI SAU EXISTENȚEI RESTANȚELOR CONFORM DATELOR SISTEMULUI INFORMAȚIONAL AUTOMATIZAT/ПОДТВЕРЖДЕНИЕ ОТСУТСТВИЯ ИЛИ НАЛИЧИЯ НЕДОИМКИ СОГЛАСНО ДАННЫХ ИНФОРМАЦИОННОЙ АВТОМАТИЗИРОВАННОЙ СИСТЕМЫ

La data emiterii prezentului certificat restanța față de bugetul public național constituie/На дату выдачи данной справки, недоимка перед национальным публичным бюджетом составляет

lei/лей

3

VALABIL PÂNĂ LA/ДЕЙСТВИТЕЛЕН ДО



Prezentul certificat este eliberat în temeiul Art. 131, alin. (5³) din Codul fiscal nr. 1163/1997, în baza datelor furnizate de Serviciul Fiscal de Stat în Portalul Guvernamental al Antreprenorului/Сертификат выдан в соответствии со ст. 131, п. (5³) Налогового кодекса №1163/1997, на основании данных, предоставленных Государственной налоговой службой на Портале Правительства Предпринимателя

Generat și semnat de Portalul Guvernamental al Antreprenorului (<https://mcabinet.gov.md>) la

Prezentul certificat este semnat electronic în conformitate cu Legea nr. 124 din 19.05.2022 /
Сертификат подписан электронной подписью в соответствии с Законом № 124 от 19.05.2022

Certificatul este descărcat de pe Portalul Guvernamental al Antreprenorului (<https://mcabinet.gov.md>) și este semnat electronic de către posesorul acestui portal și are aceeași valoare juridică ca și documentele eliberate pe suport de hârtie de către organele cu atribuții de administrare fiscală.
Verificarea autenticității semnăturii electronice poate fi realizată la adresa: <https://msign.gov.md>.

Сертификат выгружен с Правительственного Портала Предпринимателя (<https://mcabinet.gov.md>) и подписан электронной подписью владельца портала и имеет такую же юридическую силу, как и документы, выдаваемые на бумаге органами налоговой администрации.
Проверку подлинности электронной подписи можно осуществить по адресу: <https://msign.gov.md>.

ORTOFIX

Societatea cu Raspundere Limitata

Republica Moldova, Chisinau, bd. Stefan cel Mare 182.
Tel. (373) 60-808-605 email: ortofix.moldova@gmail.com
Tel/fax (373) 22-295-845
Cod fiscal 1014600000772
BC "Eximbank – Gruppo Veneto Banca"
MD36EX0000002251656584MD

05.10.2023

Către grupul de lucru pentru achiziționarea dispozitivelor medicale din cadrul Centrului Pentru Achiziții Publice Centralizate în Sănătate

Declarație

Prin prezenta, cu referire la licitația publică nr. ocds-b3wdp1-MD-1694008076735 privind Achiziția endoprotezelor conform necesităților instituțiilor medico-sanitare publice pentru anul 2023 (suplimentar), **Ortofix SRL** declară ca:

Ne obligăm să asigurăm

- tot spectrul de marimi ale protezelor pina la epuizarea completa a stocului pentru a asigura selectarea exacta a marimii necesare si siguranta actului chirurgical.
- Înlocuirea implantelor utilizate în maxim 72 ore.
- Prezentarea studiilor clinice și statistice din registre europene sau americane legate în special de rata de supraviețuire a implantelor oferite.
- În cazul unor implantate noi, instruire cu personal calificat cu instrucțiunea scrisă detaliată sau workshop online, sau asistența în timpul intervențiilor chirurgicale
- furnizarea unor implantate in minim de timp posibil in cazul aparitiei unor situatii neprevazute intraoperator
- Produsele oferite la fiecare poziție din lot vor fi de la un singur producător (cu excepția motoarelor oscilante, alezoare și lamele pentru motoare);
- Termen restant al sterilizării va fi nu mai mic de 80% la momentul livrării;
- Instrucțiunea de utilizare tradusă în limba de stat sau altă limbă de circulație internațională (Engleză) va fi prezentată la livrare;
- Mostrele ambalate si etichetate vor fi prezentate in termen de 10 zile de la solicitare
-

Pentru setul de instrumente:

1. compatibil cu endoprotezele livrate
2. va fi oferit pe toată perioada derulării contractului până la implantarea ultimei proteze existente în stocul beneficiarului
3. va fi în trusă de sterilizare specială cu indicarea codurilor de instrumente din catalog și desenelor pentru acestea.
4. va fi nou (neutilizat) În caz de defecțiune, furnizorul va fi obligat să repare sau să

- înlocuiască utilajul deteriorat în decurs de 72 ore de la solicitarea scrisă a beneficiarului.
5. Pentru implantarea tijelor femurale cimentate si necimentate se va utiliza același instrumentar.
 6. Pentru implantarea cupei dublu mobilitatea necimentate si cimentate se va utiliza același instrumentar.

Pentru motor oscilant:

1. compatibil cu endoprotezele livrate
2. va fi oferit pe toată perioada derulării contractului până la implantarea ultimei proteze existente în stocul beneficiarului.
3. va fi nou (neutilizat) În caz de defecțiune, furnizorul va fi obligat să repare sau să înlocuiască utilajul deteriorat în decurs de 72 ore de la solicitarea scrisă a beneficiarului.

**Cu respect,
Administrator Otofix Srl**

Evolutis

CREATEUR FABRICANT

Product Sheet
Stemsys®
Fiche Produit



REVISION Distal locking / Verrouillage distal
Lengths / Longueurs 210 to/a 240, 260(L) & 320mm(XL)
Collared / Avec collerette

REVISION Slotted / Fendue
Lengths / Longueurs 200 to/a 240mm
Collared and collarless / Avec ou sans collerette

**Primary Standard
1ere intention standard**
Collared or collarless / Avec ou sans collerette
HAP : Lengths / Longueurs 110 to/a 190mm
Porous Ti + HAP : Lengths / Longueurs 110 to/a 170mm

**Primary Lateralised
1ere intention Latéralisée**
Collared or collarless / Avec ou sans collerette
HAP : Lengths / Longueurs 130 to/a 190mm
Porous Ti + HAP : Lengths / Longueurs 120 to/a 170mm

**Primary cemented
1ere intention cimentée**
135° or/ou 128°
Lengths / Longueurs 120 to/a 160mm (155mm lat.)
Collarless / Sans collerette

**Neck fracture gritblasted
Fracture du col corindonnée**
Lengths / Longueurs 115 to/a 190mm
Collared / Avec collerette

Femoral implants for THA and THR indications

Implants fémoraux
pour indications de PTH et PTHR

Evolutis
MOTION INSIDE

REFERENCES

Dec 2017 / Réf. : BI_STEMSYS FP H46 (H46-432)

STEMSYS Cementless Sans ciment

Cementless dual coating Porous Ti + HA
revêtement Ti + HA

Double

Cementless HA coating
Hydroxyapatite

Lot 10

Standard	Std Collared Std à Coll.	Lateralized Latéralisé	Lat Collared Lat à coll.	Standard	Std Collared Std à Coll.	Lateralized Latéralisé	Lat Collared Lat à coll.
size / taille 7	* H45 007			H73 007			
size / taille 8	* H45 008			H73 008	H73 C008		
size / taille 9	H45 009	H45 C009	H45 L009	H73 009	H73 C009	H73 L009	H73 LC009
size / taille 10	H45 010	H45 C010	H45 L010	H73 010	H73 C010	H73 L010	H73 LC010
size / taille 11	H45 011	H45 C011	H45 L011	H73 011	H73 C011	H73 L011	H73 LC011
size / taille 12	H45 012	H45 C012	H45 L012	H73 012	H73 C012	H73 L012	H73 LC012
size / taille 13	H45 013	H45 C013	H45 L013	H73 013	H73 C013	H73 L013	H73 LC013
size / taille 14	H45 014	H45 C014	H45 L014	H73 014	H73 C014	H73 L014	H73 LC014
size / taille 15	H45 015	H45 C015	H45 L015	H73 015	H73 C015	H73 L015	H73 LC015
size / taille 16	H45 016	H45 C016	H45 L016	H73 016	H73 C016	H73 L016	H73 LC016
size / taille 18	H45 018	H45 C018	H45 L018	H73 018	H73 C018	H73 L018	H73 LC018
size / taille 20	H45 020		H45 L020	H73 020	H73 C020	H73 L020	H73 LC020

Fracture

Gritblasted Corindonné

Std Collared Std à Coll.

size / taille 8	****H73 TC008
size / taille 9	****H73 TC009
size / taille 10	****H73 TC010
size / taille 11	****H73 TC011
size / taille 12	****H73 TC012
size / taille 13	****H73 TC013
size / taille 14	****H73 TC014
size / taille 15	****H73 TC015
size / taille 16	****H73 TC016
size / taille 18	****H73 TC018
size / taille 20	****H73 TC020

Cemented A cimenter

Shiny-Polished
Poli-brillant

Std. Lat.

size / taille 9	H45 S009	H45 SL009
size / taille 10	H45 S010	H45 SL010
size / taille 11	H45 S011	H45 SL011
size / taille 12	H45 S012	H45 SL012
size / taille 13	H45 S013	H45 SL013
size / taille 14	H45 S014	H45 SL014
size / taille 15	H45 S015	H45 SL015
size / taille 16	H45 S016	H45 SL016
size / taille 18	H45 S018	

Lot 10

not validated for patients exceeding 75kgs (165lbs)

not validated for patients exceeding 80kgs (176lbs)

not validated for use with 128° NSA femoral stem

indicated only for the femoral neck fracture at the elderly

STEMSYS Revision

Split Collarless
Fendue sans
Collerette

Split Collared
Fendue à
Collerette

Distal Lock.
A verrouill.
distal

L
Distal Lock.
A verrouill.

XL
Distal Lock.
A verrouill.

Locking screw

Vis de verrouillage

size / taille 10	H45 R010	H45 RC010				ø6/4.5 lg.20	H15 SC6020
size / taille 12	H45 R012	H45 RC012	H45 R112	H45 R112L	H45 R112XL	ø6/4.5 lg.25	H15 SC6025
size / taille 14	H45 R014	H45 RC014	H45 R114			ø6/4.5 lg.30	H15 SC6030
size / taille 16	H45 R016	H45 RC016	H45 R116			ø6/4.5 lg.35	H15 SC6035
size / taille 18	H45 R018	H45 RC018	H45 R118			ø6/4.5 lg.40	H15 SC6040
size / taille 20	H45 R020	H45 RC020	H45 R120			Lot 3, Lot 12	

Femoral Heads Têtes Fémorales

Description	Size Taille	Cat. N°	Description	Size Taille	Cat. N°
Co-Cr / Chrome-Cobalt	ø28 -7mm	H10 1279	Composite Ceramic Composite	ø28 -3.5mm	H14 C1280
Co-Cr / Chrome-Cobalt	ø28 -3.5mm	H10 1280	Composite Ceramic Composite	ø28 +0mm	H14 C1281
Co-Cr / Chrome-Cobalt	ø28 +0mm	H10 1281	Composite Ceramic Composite	ø28 +3.5mm	H14 C1282
Co-Cr / Chrome-Cobalt	ø28 +3.5mm	H10 1282	Composite Ceramic Composite	ø32 -4mm	H14 C1320
Co-Cr / Chrome-Cobalt	ø28 +7mm	H10 1283	Composite Ceramic Composite	ø32 +0mm	H14 C1321
Co-Cr / Chrome-Cobalt	ø28 +10.5mm	H10 1284	Composite Ceramic Composite	ø32 +4mm	H14 C1322
Co-Cr / Chrome-Cobalt	ø32 -4mm	H10 1320	Composite Ceramic Composite	ø36 -4mm	H14 C1360
Co-Cr / Chrome-Cobalt	ø32 +0mm	H10 1321	Composite Ceramic Composite	ø36 +0mm	H14 C1361
Co-Cr / Chrome-Cobalt	ø32 +4mm	H10 1322	Composite Ceramic Composite	ø36 +4mm	H14 C1362
Co-Cr / Chrome-Cobalt	ø32 +8mm	H10 1323	Composite Ceramic Composite	ø40 -4mm	H14 C1400
Co-Cr / Chrome-Cobalt	ø36 -4mm	H10 1360	Composite Ceramic Composite	ø40 +0mm	H14 C1401
Co-Cr / Chrome-Cobalt	ø36 +0mm	H10 1361	Composite Ceramic Composite	ø40 +4mm	H14 C1402
Co-Cr / Chrome-Cobalt	ø36 +4mm	H10 1362			
Co-Cr / Chrome-Cobalt	ø36 +8mm	H10 1363			

STEMSYS instrumentation sets:
primary set, slotted revision set, and
distal locking jig set.

Instrumentations STEMSYS



Mentions légales : V8 à 8 de PY di d 8e9or8 o88888 à onl : à 8e9 nr8 or ml 88r TTTéov : 8 8e : 7x8 l 7u7e 89r8 87a l 7r8 99 x8 aeS. è :
@ 79x8 aS. è : 8e : 7x8 l 8e8 ol 7u7e 89r8 aeSc. or x ul énr 8xéé x r78e63
Vr8 à 8 de PY di d 8e9or8 ré nul 7r @ 7x 88: 7 én à l x or 8e : 8 nr 79 ver 8 nee883v87a l 9eé8 8: 7x 88 www.ameli.fr2
Tmkpr : omv n89m x n88Au nv9v r9A trmi 9nv9 nu nv9tn8 iv89: k9wv8 u nv9wvAn8 8: ti v99kml : 9tr8i 9w ivkt: 8ml i v8 tm
kwvl r9wvnu nv9l : NV 8i iv8ry: ml i v8 tm u i v: nt l m9rkpvry: mwvA i 9vml Atr A ti u r8mmv xti kml : x w l : 9w. l r8xwvj tmv
9Atkpi omv nv98: tm8r9m 2n vt: 98r7i vkn8kw 2

Materials / Matériaux :

Cementless stems: Titanium alloy TA6V according ISO5832-3 + gritblasted or Calcium Hydroxyapatite or T40 titanium + Calcium

Hydroxyapatite

Cemented stems: High nitrogen content stainless steel according ISO5832-9

Femoral heads: Co-Cr according ISO5832-12 or Pure alumina according ISO6474-1 or Composite Ceramic according ISO6474-2

vacuum packaging: Gamma ray sterilised



Avenue de la Libération, 42720 Briennon, France
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www.evolutisfrance.com

E v o l u t i s

C R E A T E U R F A B R I C A N T

Product Sheet
CAPITOLE®
Fiche Produit



Capitole R



Capitole T

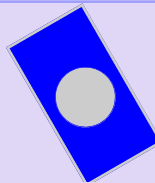


Capitole I

*Dual Mobility acetabular Cup for
primary and revision indications*

Cupule acétabulaire à
double mobilité pour
arthroplastie primaire ou
de révision

Evolutis
MOTION INSIDE

12/14**FEMORAL****HEADS***Stainless Steel, Cobalt-Chrome, Ceramic***Stainless steel ISO5832-9 standard**

H11 1220	Stainless steel Ø 22.2 mm short -2
H11 1221	Stainless steel Ø 22.2 mm medium 0
H11 1222	Stainless steel Ø 22.2 mm long +2
H11 1279	Stainless steel Ø 28 mm extra short -7*
H11 1280	Stainless steel Ø 28 mm short -3.5
H11 1281	Stainless steel Ø 28 mm medium 0
H11 1282	Stainless steel Ø 28 mm long +3.5
H11 1283	Stainless steel Ø 28 mm extra long +7
H11 1320	Stainless steel Ø 32 mm short -4
H11 1321	Stainless steel Ø 32 mm medium 0
H11 1322	Stainless steel Ø 32 mm long +4
H11 1323	Stainless steel Ø 32 mm extra long +8

Composite Alumina ISO 6474 biolox

H14 C1280	Alumina Composite Ø 28 mm short -3.5
H14 C1281	Alumina Composite Ø 28 mm med 0
H14 C1282	Alumina Composite Ø 28 mm long +3.5
H14 C1283	Alumina Composite Ø 28 mm long +7
H14 C1320	Alumina Composite Ø 32 mm short -3.5
H14 C1321	Alumina Composite Ø 32 mm medium 0
H14 C1322	Alumina Composite Ø 32 mm long +3.5
H14 C1323	Alumina Composite Ø 32 mm long +8**
H14 C1360	Alumina Composite Ø 36 mm short -4
H14 C1361	Alumina Composite Ø 36 mm med 0
H14 C1362	Alumina Composite Ø 36 mm long +4
H14 C1363	Alumina Composite Ø 36 mm extra long +8**
H14 C1400	Alumina Composite Ø 40 mm short -4
H14 C1401	Alumina Composite Ø 40 mm med 0
H14 C1402	Alumina Composite Ø 40 mm long +4
H14 C1403	Alumina Composite Ø 40 mm long +8**

Cobalt-Chrome ISO5832-12 standard**Lot 10**

H10 1220	Cobalt Chrome Ø 22.2 mm short -2
H10 1221	Cobalt Chrome Ø 22.2 mm medium 0
H10 1222	Cobalt Chrome Ø 22.2 mm long +2
H10 1223	Cobalt Chrome Ø 22.2 mm long +4
H10 1280	Cobalt Chrome Ø 28 mm short -3.5
H10 1281	Cobalt Chrome Ø 28 mm medium 0
H10 1282	Cobalt Chrome Ø 28 mm long +3.5
H10 1283	Cobalt Chrome Ø 28 mm extra long +7
H10 1320	Cobalt Chrome Ø 32 mm short -4
H10 1321	Cobalt Chrome Ø 32 mm medium 0
H10 1322	Cobalt Chrome Ø 32 mm long +4
H10 1323	Cobalt Chrome Ø 32 mm extra long +8
H10 1360	Cobalt Chrome Ø 36 mm short -4
H10 1361	Cobalt Chrome Ø 36 mm medium 0
H10 1362	Cobalt Chrome Ø 36 mm long +4
H10 1363	Cobalt Chrome Ø 36 mm extra long +8

Alumina ISO 6474 standard

H14 1270	Alumina Ceramic Ø 28 mm short -3.5
H14 1271	Alumina Ceramic Ø 28 mm medium 0
H14 1272	Alumina Ceramic Ø 28 mm long +3.5
H14 1310	Alumina Ceramic Ø 32 mm short -4
H14 1311	Alumina Ceramic Ø 32 mm medium 0
H14 1312	Alumina Ceramic Ø 32 mm long +4
H14 1350	Alumina Ceramic Ø 36 mm short -4
H14 1351	Alumina Ceramic Ø 36 mm medium 0
H14 1352	Alumina Ceramic Ø 36 mm long +4

additional sizes on request

References

CAPITOLE dual mobility acetabular cup Cupule acétabulaire à double mobilité CAPITOLE

Shell ø Cupule	Press-fit I	2 pegs T 2 plots T	Cemented C Cimenté C	Revision R	Revision RA
ø45	H51 I245	H51 T245	H51 C045	-	-
ø47	H51 I247	H51 T247	H51 C047	H51 R247	H51 RA247
ø49	H51 I249	H51 T249	H51 C049	H51 R249	H51 RA249
ø51	H51 I251	H51 T251	H51 C051	H51 R251	H51 RA251
ø53	H51 I253	H51 T253	H51 C053	H51 R253	H51 RA253
ø55	H51 I255	H51 T255	H51 C055	H51 R255	H51 RA255
ø57	H51 I257	H51 T257	H51 C057	H51 R257	H51 RA257
ø59	H51 I259	H51 T259	H51 C059	H51 R259	H51 RA259
ø61	H51 I261	H51 T261	H51 C061	H51 R261	H51 RA261
ø63	H51 I263	H51 T263		H51 R263	H51 RA263
ø65	-	-	Lot 10	H51 R265	-

CAPITOLE dual mobility liner Insert à double mobilité CAPITOLE

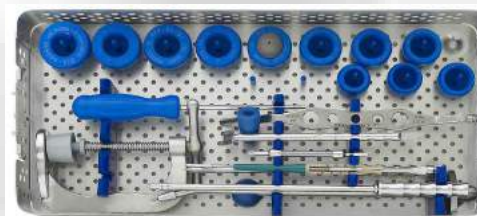
Liner ø Insert	Inner ø Interne 22.2 PE	Inner ø Interne 28 PE	Inner ø Interne 28 Ceramic
ø45	H51 M2245	-	-
ø47	H51 M2247	H51 M2847	-
ø49	H51 M2249	H51 M2849	-
ø51	H51 M2251	H51 M2851	H61 MA2850
ø53	H51 M2253	H51 M2853	H61 MA2852
ø55	H51 M2255	H51 M2855	H61 MA2854
ø57	H51 M2257	H51 M2857	H61 MA2856
ø59	H51 M2259	H51 M2859	H61 MA2858
ø61	H51 M2261	H51 M2861	H61 MA2860
ø63	H51 M2263	H51 M2863	-
ø65	H51 M2265	H51 M2865	-

Screws and Pegs Vis et plots

Description	ø (mm)	L. (mm)	Cat N°
Cortical screw / Vis corticale	5	35	H16 S5035
Cortical screw / Vis corticale	5	40	H16 S5040
Cortical screw / Vis corticale	5	45	H16 S5045
Cortical screw / Vis corticale	5	50	H16 S5050
Cortical screw / Vis corticale	5	55	H16 S5055
Cortical screw / Vis corticale	5	60	H16 S5060
Tripode pegs (set of 2) Plots Tripode (par 2)	7	15	H51 P2715



Instrumentation
CAPITOLE
H52 9100



Capitole I



Capitole T



Capitole R



Capitole RA

Mentions légales :
Les implants CAPITOLE sont des dispositifs médicaux implantables de classe III indiqués pour les arthroplasties primaires totales (PTH) ou en révision (PTHR) de la hanche selon la version.
Les implants CAPITOLE sont pris en charge par l'assurance maladie. Informations sur www.ameli.fr.
Le chirurgien est expressément invité à lire attentivement les instructions mentionnées sur la notice d'utilisation incluse dans le conditionnement du DMI, ainsi que le manuel de technique opératoire délivré à la mise en place du produit ou disponible en téléchargement sur le site www.evolutisfrance.com.

Materials / Matériaux :
Cups: High Nitrogen Content Stainless steel according ISO 5832-9 coated with porous T40 and Calcium Hydroxyapatite
Liners: UHMWPE according ISO 5834-1 & 2
Screws: Stainless steel according ISO 5832-1
Pegs: titanium alloy (TA6V) according ISO 5832-3
Packaging: Sterilized under Gamma irradiation, VacUpac packaging
Cupules : Acier inoxydable à Haute Teneur en Azote selon ISO 5832-9 revêtu T40 poreux et Hydroxyapatite
Inserts : UHMWPE selon ISO 5834-1 et 2
Vis : Acier inoxydable selon ISO 5832-1
Plots : alliage de titane (TA6V) selon ISO 5832-3
Conditionnement : Stérilisé sous rayonnement Gamma, conditionnement VacUpac



Designed and
Manufactured in
France

Evolutis

CREATEUR FABRICANT

Product Sheet
**DM Cemented
& Cross-shell**
Fiche Produit



*Dual Mobility Cemented
acetabular Cup and Protrusio cross-shell*

Cupule acétabulaire à double
mobilité à Ciment et Croix de
reconstruction

Evolutis
MOTION INSIDE

E v o l u t i s
C R E A T E U R F A B R I C A N T



CAPTIV

press fit dual mobility cup



POLYETHYLENE

Crosslinked Polyethylene



CAPITOLE

Cemented dual mobility cup

10 years clinical use

CAPTIV DM[®]
CAPITOLE[®]

DUAL MOBILITY: A GUARANTEE OF STABILITY

CAPTIV DM :

Dual Mobility ensures a high degree of articular stability and large range of motion. Primary stability is ensured by an excellent peripheral press fit.

CAPTIV specifications :

- The cups are made from **nitrogen enriched M30 stainless steel** this steel is 40% more resistant than 316L and much less prone to corrosion. It avoids the risk of galvanic corrosion with titanium coating.
- The cup is entirely coated with a **layer of 150 microns of porous titanium with a second coating of 100 microns of osteoconductive hydroxyapatite**
- Peripheral pressfit is proportional to size with an average of 1mm.
- The pole is congruent with bone reamed, it is recommended to use the same size cup as the reamer ensuring the press fit.



CAPITOLE :

A complete range of Dual Mobility cups :
press-fit and cemented Dual Mobility ensures a high degree of articular stability and large ranges of motion.

CAPITOLE specifications :

The cemented CAPITOLE C cup has a mobile insert for enhanced stability in different indications.

- Stainless steel cup, **mirror polished inside and on the outside.**
- Reaming and cup size are size for size.
- The cup has incorporated **spacers which guarantee a regular cement mantle according to Charnley principles.**

The **peripheral rim is flanged which ensures correct centring of the cup** and cement pressurisation. The cement escapes via 3 vents.

Cement mantle and pressurisation is therefore of good quality.



MOBILE INSERT :

- The chamfered mobile insert is strongly retentive in order to prevent the head from dislocating.

Test CRITT (Independent Laboratory) :105,5daN pull out (1 daN equivalent to 1Kg).

- The polyethylene sphere behaves like a big head of at least 40 mm which ensures a large range of motion and stability which has been shown to be above 99,8%.

- Internal diameter for different heads. :

*Polyethylene for Ø28 mm heads.

- The range of sizes extends from Ø46mm to Ø62 mm (Ø47mm to Ø61mm Cemented). Polyethylene wear of the retentive collar is reduced by the self centring anti capsizing insert which automatically realigns itself in the axis of constraints.



PEXEL® Polyethylene, "moderately crosslinked"

Ultra high molecular weight polyethylene (over 7 million), only made by extrusion. Cross linkage is obtained by using a moderate level of irradiation of about 40 kGy under vacuum.

Vac U Pac packaging is done under vacuum in a foil pouch free of oxygen, (seal validation undertaken by the Laboratoire National d'Essai (LNE))

Wear test undertaken by CERAH laboratory on a CAPITOLE T cup with an aged polyethylene:

- After 5 000 000 de cycles, the amount of mass lost was 131,7 mg, which corresponds to a penetration rate of 0,05 mm/year ; ie 5 times less than with standard polyethylene.

- The graph represents mass lost during walking cycles, getting up from a chair and stairs.



E v o l u t i s
C R E A T E U R F A B R I C A N T



*Dual
Mobility
Experience*



Captiv® DM



*Dual Mobility
Acetabular Cup*

*Cupule à Double
Mobilité*

Evolutis
MOTION INSIDE

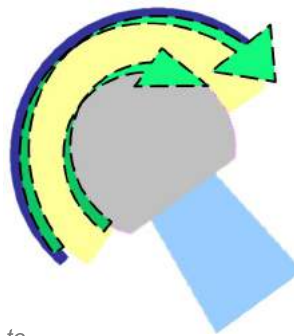


Created in St Etienne (France) in the mid 70's, the dual mobility concept has progressively evolved to provide a comprehensive answer to both patients and surgeons expectations in terms of security of use and longevity. Due to a very high intrinsic joint stability ⁽¹⁾ and a resistance to wear at least equivalent to conventional fixed bearings PE friction devices ⁽²⁾, the dual mobility cups account for more than 25% of the acetabular cups implanted in France.



Imaginée à St Etienne au milieu des années 70, la double mobilité a su évoluer pour apporter une réponse cohérente aux attentes des patients et de leur chirurgien pour plus de sécurité et de longévité.

En raison d'une stabilité intra-articulaire très importante ⁽¹⁾ et d'une résistance à l'usure au moins équivalente aux couples PE classiques ⁽²⁾, les cupules à double mobilité représentent aujourd'hui plus de 25% des implants acétabulaires utilisés en France.



1st Mobility: head/liner from 0 to 60° (28mm head with Ø10mm neck)

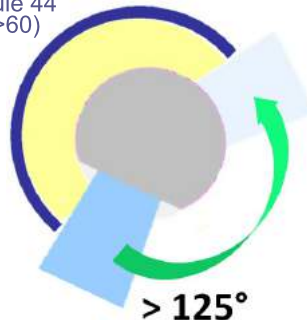
2nd Mobility: liner/cup from 60 to > 125°

Mobilité 1 : tête/insert de 0 à 60° (tête 28mm sur col de Ø10mm)

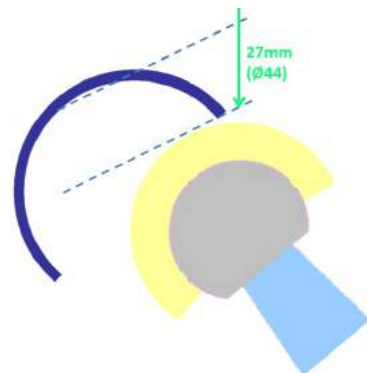
Mobilité 2 : insert/cupule de 60 à >125°

ROM > 125° for cup 44 (up to 140° for larger cups)

Mobilité >125° pour cupule 44 (jusqu'à 140° pour cup. >60)



> 125°



Stability: large jump gap > 27mm starting cup 44

Stabilité : Jump gap important > 27mm dès la taille 44

Main indications:

- primary arthritis for patients over 70
- fractured femoral necks in active patients
- primary arthritis for non compliant patients (dementia, alcohol...)
- primary arthritis for joint laxity (neuromuscular disorders, cerebral palsy, rheumatoid arthritis...)
- hip prosthesis revisions

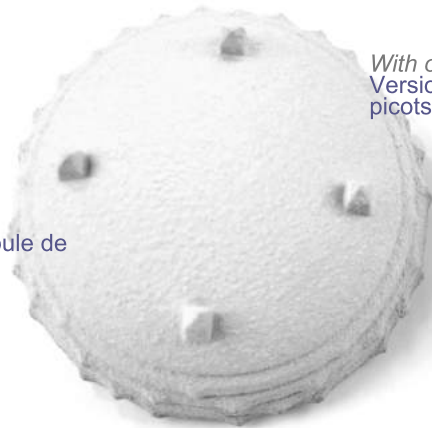
Indications principales :

- arthroses primaires chez le patient de plus de 70 ans
- fractures de col fémoral chez le patient actif
- arthropathies sévères associées à une laxité intra-articulaire (déficients neuromusculaires...)
- arthropathies sévères chez les patients à comportement irrationnel (pathologies nerveuses, comportements addictifs...)
- révisions de prothèses de hanche

(1) Survival of the cementless Bousquet dual mobility cup: Minimum 15 year follow up of 437 total hip arthroplasties. C. Lautridou, B.Lebel, G.Buridin, C.Vielpeau. University Hospital of Caen, France. Publication RCO, 2008, 94, 731 – 739

(2) Dual articulation retentive acetabular liners and wear: surface analysis of 40 retrieved polyethylene implants. P.Adam, F.Farizon, M-H Fessy. University Hospital St Etienne, France. Publication : RCO, 2005, 91, 627-636

Cup size from
Ø44 to 62
Gamme de cupule de
Ø44 à 62



With or without spikes
Versions avec et sans
picots



Dual coating of Porous
titanium and
Hydroxyapatite
Revêtement bi-couche
T40 poreux et
Hydroxyapatite

CAPTIV DM incorporates the knowledge acquired from almost 40 years of clinical use in hundreds of thousands of DM cups implanted worldwide:

- M30NW Iso 5832-9 forged stainless steel (improved friction characteristics)
- Dual coating of Porous titanium and Hydroxyapatite
- Equatorial press-fit completed with 3 rows of anchoring teeth
- Protrusion of the PE liner through reduction of cup thickness at the pole
- Moderately crosslinked PEXEL® polyethylene
- Liner including "positive excentration" design
- VacUpac conservation technology

CAPTIV DM intègre les acquis d'une expérience de presque 40 ans sur plusieurs centaines de milliers d'implants dans le monde :

- matériau M30NW Iso 5832-9 forgé (amélioration des caractéristiques de frottement)
- double revêtement titane poreux et hydroxyapatite
- macrostructure à 3 rangées de dentures associée à un sur-dimensionnement équatorial
- protrusion du centre de l'insert par réduction de la toile au niveau polaire
- insert polyéthylène PEXEL® moyennement réticulé
- insert à conception "positive excentration"
- technologie de conservation VacUpac



UHMWPE with positive excentration:
dynamic control of the "third"
articulation

Inserts UHMWPE à excentration
positive : contrôle actif de la "3ème"
articulation



PEXEL® polyethylene

- initial molecularweight exceeding 7 millions of g/mole
- 40 kGy minimum gamma irradiation under vacuum creating crosslinking
- VacUpac vacuum conservation
- 50% Wear reduction (CERAH test according ISO 14242-1 and 14242-2, 5 millions cycles on shelf aged implants) in comparison to a conventional polyethylene.

Polyéthylène PEXEL®

- poids moléculaire initial supérieur à 7 millions de g/mole
- réticulation gamma à 40 kGy minimum
- conservation sous-vide VacUpac
- 50% de réduction d'usure (Test CERAH selon ISO 14242-1 et 14242-2, à 5 millions de cycles sur implants vieilliss sur étagère) par rapport à un polyéthylène conventionnel.

PEXEL® polyethylene liners Ø22 or 28 in
UHMWPE
Inserts polyéthylène PEXEL® en Ø22. ou
28 en UHMWPE

Cupules CAPTIV® Acetabular cups

Description	Ø	Réf. Cat N°	Description	Ø	Réf. Cat N°
HA ss ciment Press-Fit / C. less HA Press-Fit	44	H29 DM044	HA ss. ciment av. picots / C. less HA with spikes	44	H29 DM144
HA ss ciment Press-Fit / C. less HA Press-Fit	46	H29 DM046	HA ss. ciment av. picots / C. less HA with spikes	46	H29 DM146
HA ss ciment Press-Fit / C. less HA Press-Fit	48	H29 DM048	HA ss. ciment av. picots / C. less HA with spikes	48	H29 DM148
HA ss ciment Press-Fit / C. less HA Press-Fit	50	H29 DM050	HA ss. ciment av. picots / C. less HA with spikes	50	H29 DM150
HA ss ciment Press-Fit / C. less HA Press-Fit	52	H29 DM052	HA ss. ciment av. picots / C. less HA with spikes	52	H29 DM152
HA ss ciment Press-Fit / C. less HA Press-Fit	54	H29 DM054	HA ss. ciment av. picots / C. less HA with spikes	54	H29 DM154
HA ss ciment Press-Fit / C. less HA Press-Fit	56	H29 DM056	HA ss. ciment av. picots / C. less HA with spikes	56	H29 DM156
HA ss ciment Press-Fit / C. less HA Press-Fit	58	H29 DM058	HA ss. ciment av. picots / C. less HA with spikes	58	H29 DM158
HA ss ciment Press-Fit / C. less HA Press-Fit	60	H29 DM060	HA ss. ciment av. picots / C. less HA with spikes	60	H29 DM160
HA ss ciment Press-Fit / C. less HA Press-Fit	62	H29 DM062	HA ss. ciment av. picots / C. less HA with spikes	62	H29 DM162

Inserts DM CAPTIV® DM Liners

Ø de cupule Ø of cup	Description	Tête / Head 22.2	Tête / Head Ø 28
44	Insert UHMWPE PEXEL UHMWPE liner	H51 M2245	
46	Insert UHMWPE PEXEL UHMWPE liner	H51 M2247	H51 M2847
48	Insert UHMWPE PEXEL UHMWPE liner	H51 M2249	H51 M2849
50	Insert UHMWPE PEXEL UHMWPE liner	H51 M2251	H51 M2851
52	Insert UHMWPE PEXEL UHMWPE liner	H51 M2253	H51 M2853
54	Insert UHMWPE PEXEL UHMWPE liner	H51 M2255	H51 M2855
56	Insert UHMWPE PEXEL UHMWPE liner	H51 M2257	H51 M2857
58	Insert UHMWPE PEXEL UHMWPE liner	H51 M2259	H51 M2859
60	Insert UHMWPE PEXEL UHMWPE liner	H51 M2261	H51 M2861
62	Insert UHMWPE PEXEL UHMWPE liner	H51 M2263	H51 M2863



Instrumentation CAPTIV® Instrument Set

Description	H30 9102 Droit/Straight	H30 9104 Courbe/Curved	Description	H30 9102 Droit/Straight	H30 9104 Courbe/Curved
Plateau avec couvercle / Tray with Lid	H30 9002	H30 9004	Préhenseur de cotyle Ø46-47 cup impaction tip	H52 2247	H52 P47
Corps d'impacteur / Cup impactor (body)	H52 007	-	Préhenseur de cotyle Ø48-49 cup impaction tip	H52 2249	H52 P49
Vis d'impacteur / Cup impactor (Screw)	H52 008	-	Préhenseur de cotyle Ø50-51 cup impaction tip	H52 2251	H52 P51
Manche impacteur courbe / Curved impaction	-	H52 036	Préhenseur de cotyle Ø52-53 cup impaction tip	H52 2253	H52 P53
Tige d'orientation Ø18 Orientation axis	H03 013	H76 019	Préhenseur de cotyle Ø54-55 cup impaction tip	H52 2255	H53 P55
Presse à insert / Liner press	H52 033		Préhenseur de cotyle Ø55-56 cup impaction tip	H52 2257	H52 P57
Vis de presse à insert / Liner press screw	H52 030		Préhenseur de cotyle Ø57-58 cup impaction tip	H52 2259	H52 P59
Centreur de tête / Femoral head centralizer	H52 031		Préhenseur de cotyle Ø59-60 cup impaction tip	H52 2261	H52 P61
Embout poussoir d'insert / Liner pusher tip	H52 035		Préhenseur de cotyle Ø62-63 cup impaction tip	H52 2263	H52 P63
Réducteur d'essai Ø22.2 trial insert adaptor	H52 2228		Cotyle d'essai Ø44 trial cup	H03 0244	
Manche impacteur M10 Impaction shaft	H03 036		Cotyle d'essai Ø46 trial cup	H03 0246	
Embout poussoir de cupule / Cup impaction tip	H03 037		Cotyle d'essai Ø48 trial cup	H03 0248	
Sphère d'impaction / Impaction spherical tip	H62 005		Cotyle d'essai Ø50 trial cup	H03 0250	
Insert d'essai Ø 22/44-45 trial liner	H52 M2245		Cotyle d'essai Ø52 trial cup	H03 0252	
Insert d'essai Ø 28/46-47 trial liner	H52 M2847		Cotyle d'essai Ø54 trial cup	H03 0254	
Insert d'essai Ø 28/48-49 trial liner	H52 M2849		Cotyle d'essai Ø56 trial cup	H03 0256	
Insert d'essai Ø 28/50-51 trial liner	H52 M2851		Cotyle d'essai Ø58 trial cup	H03 0258	
Insert d'essai Ø 28/52-53 trial liner	H52 M2853		Cotyle d'essai Ø60 trial cup	H03 0260	
Insert d'essai Ø 28/54-55 trial liner	H52 M2855		Cotyle d'essai Ø62 trial cup	H03 0262	
Insert d'essai Ø 28/56-57 trial liner	H52 M2857				
Insert d'essai Ø 28/58-59 trial liner	H52 M2859				
Insert d'essai Ø 28/60-61 trial liner	H52 M2861				
Insert d'essai Ø 28/62-63 trial liner	H52 M2863				
Préhenseur de cotyle Ø44-45 cup impaction tip	H52 2245	H52 P45			

Options	Réf. Cat N°
Tige d'orientation Ø12 Orientation axis (Tommy bar)	H03 007
Instrum. fraises à cotyle / Grater Reamer set	H03 9100



Mentions légales :

Les implants CAPTIV DM sont des dispositifs médicaux implantables de classe III indiqués pour les arthroplasties primaires totales (PTH) de la hanche.
Les implants CAPTIV DM sont pris en charge par l'assurance maladie.
Le chirurgien est expressément invité à lire attentivement les instructions mentionnées sur la notice d'utilisation incluse dans le conditionnement du DMI, ainsi que le manuel de technique opératoire délivré à la mise en place du produit ou disponible en téléchargement sur le site www.evolutisfrance.com.

Materials / Matériaux :

Cups: High Nitrogen content Stainless Steel according ISO 5832-9 with T40 and calcium hydroxyapatite coatings
Polyethylene liners: UHMWPE according ISO 5834-1 & 2 moderately crosslinked
Packaging: Sterilized under Gamma irradiation, VacUpac packaging
Cupules : Acier Inoxydable à haute teneur en azote selon ISO 5832-9 revêtu T40 et Hydroxyapatite de Calcium
Inserts polyéthylène : UHMWPE selon ISO 5834-1 et 2 modérément réticulé
Conditionnement : Stérilisé sous rayonnement Gamma, conditionnement VacUpac



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