

DISTRIBUIMOS... ADLER & Surgival ORTHO





CUSTOM IMPLANT FOR ONCOLOGY

Cup Fixa Ti-Por



Cup Fixa



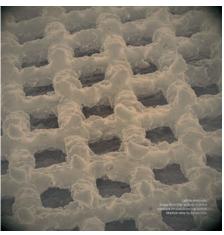
The uncemented cup with equatorial primary "press-fit" fixation is considered to be the best solution for prosthesis surgery of the acetabulum.

In addition to exploiting this safe mechanical concept which ensures primary fixation, the Fixa Ti-Por[®] cup is realized by means of a special and innovative production technique (Electron Beam Melting EBM) which makes it possible to obtain optimum porosity at the peripheral level, ideal for the trabecular graft and consequently to ensure secondary osteointegration. The cup is made in a single machining operation and has a reticular structure with interspaces of about 700 micron (Photo A) throughout the outer surface. This dimension, as is clear from literature, allows the bony trabeculae to bring about excellent grafting, favouring the growth of new bony tissue (bone in growth). The low profile hemispherical cup made of titanium alloy (Ti6A14V ISO 5832/3 ASTM F136) makes it possible to always obtain an excellent "press-fit" on its hemisphere, where the mechanical holding forces of the acetabulum act in the best possible manner. A 1 mm increase of the radius, in relation to the acetabular reamers (except for the apical area) guarantees a primary stabilization also in the most difficult diseases, such as, for example, dysplasia.

The screw for closing the apical opening meant for fixing the impactor is supplied together with the cup. Five threaded holes are provided on the outer surface (3 holes for size 44), with an equal number of plugs screwed in, for use, if necessary, of screws for cup (diam. 6.5 mm), in cases where supplementary fixing to the iliac bone is necessary.

The plugs can be removed easily using a screwdriver included with the instruments set.

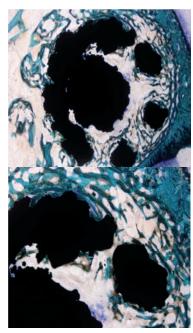
Ceramic inserts can be used to obtain extraordinary resistance to wear, as is shown by laboratory tests and by decades of clinical "follow-ups".



(A)

Pilot Study Conducted At The Laboratory of surgical preclinical studies of the Istituto Ortopedico Rizzoli directed by Prof. R. Giardino in collaboration with the VII division of traumatologic orthopaedic surgery directed by Prof. A.giunti.





Cylindrical biomedical implant implanted in the trabecular bone of distal femur of animal

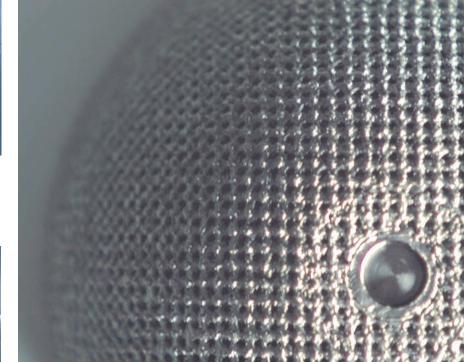
DIM. 2X

Two weeks from the surgery, spongy bone is observed in the repair phase with thin and dense trabeculae surrounding the implant and penetrating into the space created by the macroporosity of the biomaterial.

The bone tissue is in direct contact with the biomaterial, without fibrous tissue in between.

DIM. 4X





Electron Beam Melting EBM



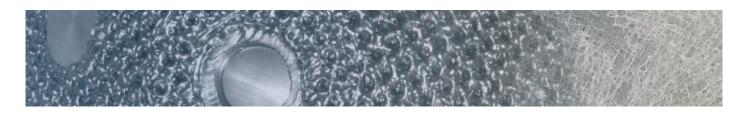
Thanks to the latest generation ceramics, it is possible to use thin inserts which allow the use of heads with large diameter (32, 36 and 40 mm). The latter offer a wider range of articular movement of the hip, reducing "impingement" and dislocation phenomena.

The ceramic insert fixing system consists of a conical fit on metal shell in order to ensure a tested mechanical grip.

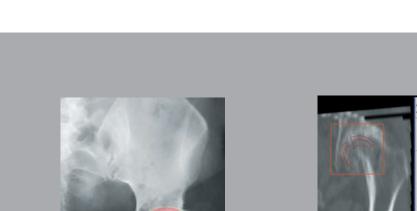
It is also possible to use polyethylene and reticulated polyethylene inserts, available in versions with and without 15° anti-dislocation lip and with retention. The system of total contact of the insert on smooth metal and the original technique for blocking the insert ensure a high-performance cup, providing the operator with a valid solution.

With the same technical solution of ceramic inserts, it is possible to use metal inserts in combination with metal heads also available in diameters 32, 36 and 40 mm.

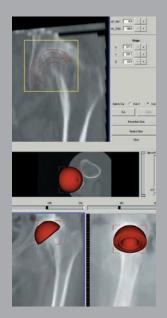
The use of ceramic inserts, divided into four groups, A to D, has made it possible to reduce the thickness of the titanium cup walls and consequently also use small sized polyethylene inserts with acceptable thickness conforming to the standards in force.











Surgical Study

Ø 54

Ø46

Special overhead transparencies or C.T. reconstructions can be used to define the size and centre of rotation of the cup to be impacted in the acetabulum, taking care to avoid damaging the cranial cortex and without sinking medially with respect to the bottom of the cup. In case of doubt regarding the size of

the prosthesis cup to be used, first measure the femoral head removed and add 4/6 mm; it will thus be possible to draw the outline of the FIXA Ti-Por[®] cup to be implanted and define the optimum centre of rotation.

Cup Fixa -Por



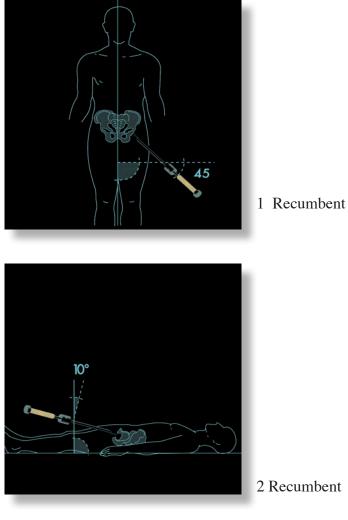
Reaming the Acetabulum

After removing the periacetabular capsular tissue residue, start reaming the acetabulum using the special "basket-shaped" hemispherical reamer.

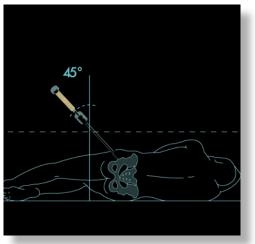
It is possible to start with reamers having smaller diameter, bearing in mind that it is not advisable to start with diameters excessively smaller than those of the acetabulum (except for dysplasic acetabulum, for which the use of reamers having small diameter is necessary to deepen the cavity in the direction of the paleocotyl).

Proceed with the reamer having greater diameter to remove the fibrous or ivory-like tissue also on the outermost surface of the acetabulum.

Then, just sink the reamer until it comes in contact with the acetabular bone covering.

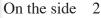


2 Recumbent



On the side 1





NOTE: The Fixa Ti-Por[®] cup has a real diameter that's 2mm bigger than its nominal one. Its Ti-Por® surface is extremely rough and it provides an exceptional primary stability. Because of that it's recommended to select a cup with a size (Nominal Diameter) 2 mm smaller Vs the last reamer used.

TRIAL CUP

After reaming the surgeon can check the hemisphericity of the acetabular cavity by means of a trial cup. Fixa Ti-Por[®] trial cups have the same geometrical dimensions as the real implants. Therefore the surgeon will have to select a trial cup 2 mm smaller Vs the last reamer used, and then implant the final acetabular component having the same size as the trial he used.

INSERTING THE FIXA Ti-Por® CUP

To position the acetabular prosthetic component properly, it is advisable to ensure a lateral inclination of the cup between 40° and 45° and its anteversion between 10° and 15°. This can be done by using the impactor by using the angular rods supplied, at the surgeon's discretion.

After ascertaining the position of the cup, sink it into the acetabulum until it is covered by the bony margins.

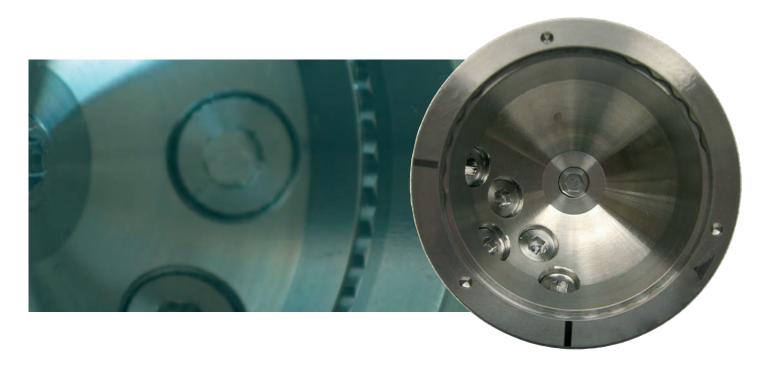
Then remove the impactor and check through the apical hole to ensure that the cup is actually sunk inside; if there is remaining space, complete the positioning of the cup by using the final hemispherical impactor.

The primary stability of the FIXA Ti-Por[®] cup is guaranteed by the "press-fit" but, if necessary, because of sclerotic or deformed bone, self-tapping screws can be used in the holes provided, after taking care to remove the pre-assembled plugs.



TRIAL INSERT

This makes it possible to evaluate the correct final positioning of the FIXA Ti-Por[®] cup, as well as the geometry of the joint. In fact, by means of special trial inserts screwed to the apical hole of the prosthetic component implanted by means of the screw pre-assembled to the insert, it is possible to carry out a trial reduction and check all the main articular parameters.



FINAL INSERT

After selecting the insert to be implanted, after closing the apical hole by means of the screw provided, for the ceramic insert and metal insert, position this manually in the prosthetic cup and impact; for the polyethylene insert, use the special instrument provided for insertion.



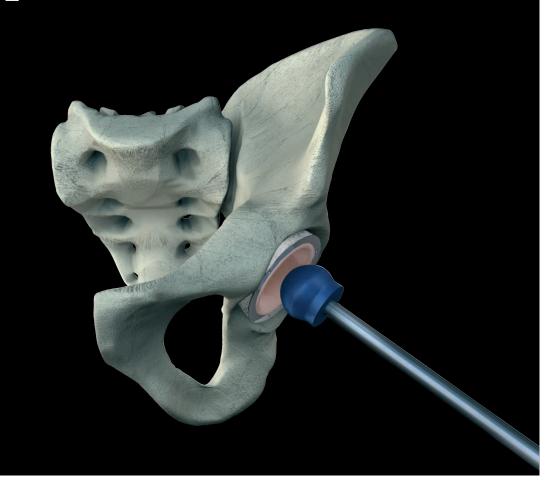
TETT



If it is found to be necessary to remove the ceramic or metal insert, use the extractors provided, taking care to collimate the two resting points with the three holes situated on the equatorial plane of the prosthetic cup and impact.



Cup Fixa T-PDR®



IMPLANT – INSTRUMENT CODES

IMPLANTS

0753144	SIZE. 44	FIXA Ti-Por [®] CUP	GR.A
0753146	SIZE. 46	FIXA Ti-Por® CUP	GR.A
0753148	SIZE. 48	FIXA Ti-Por® CUP	GR.A
0753350	SIZE. 50	FIXA Ti-Por® CUP	GR. B
0753352	SIZE. 52	FIXA Ti-Por® CUP	GR. B
0753454	SIZE 54	FIXA Ti-Por® CUP	GR. C
0753456	SIZE 56	FIXA Ti-Por® CUP	GR. C
0753558	SIZE 58	FIXA Ti-Por® CUP	GR. D
0753560	SIZE 60	FIXA Ti-Por® CUP	GR. D
0753562	SIZE 62	FIXA Ti-Por® CUP	GR. D
0753564	SIZE 64	FIXA Ti-Por® CUP	GR. D
0753566	SIZE 66	FIXA Ti-Por® CUP	GR. D

0832811	NEUTRAL PE INSERT	D. 28	GR.A
0832813	NEUTRAL PE INSERT	D. 28	GR. B
0832814	NEUTRAL PE INSERT	D. 28	GR. C
0832815	NEUTRAL PE INSERT	D. 28	GR. D
0842811	15° PE INSERT	D. 28	GR.A
0842813	15° PE INSERT	D. 28	GR. B
0842814	15° PE INSERT	D. 28	GR. C
0842815	15° PE INSERT	D. 28	GR. D
0852811	NEUTRAL PE RETAINING INSERT	D. 28	GR.A
0852813	NEUTRAL PE RETAINING INSERT	D. 28	GR. B
0852814	NEUTRAL PE RETAINING INSERT	D. 28	GR. C
0852815	NEUTRAL PE RETAINING INSERT	D. 28	GR. D

0832821	NEUTRAL RETICULATED PE INSERT	D. 28	GR.A
0833223	NEUTRAL RETICULATED PE INSERT	D. 32	GR. B
0833224	NEUTRAL RETICULATED PE INSERT	D. 32	GR.C
0833225	NEUTRAL RETICULATED PE INSERT	D. 32	GR. D
0833624	NEUTRAL RETICULATED PE INSERT	D. 36	GR.C
0833625	NEUTRAL RETICULATED PE INSERT	D. 36	GR. D
		1	
0842821	15° RETICULATED PE INSERT	D. 28	GR.A
0843223	15° RETICULATED PE INSERT	D. 32	GR. B
0843224	15° RETICULATED PE INSERT	D. 32	GR.C
0843225	15° RETICULATED PE INSERT	D. 32	GR. D
0843624	15° RETICULATED PE INSERT	D. 36	GR.C
0843625	15° RETICULATED PE INSERT	D. 36	GR. D
		İ	1
0813201	DELTA CER. INSERT	D. 32	GR.A
0813603	DELTA CER. INSERT	D. 36	GR. B
0813604	DELTA CER. INSERT	D. 36	GR.C
0813605	DELTA CER. INSERT	D. 36	GR. D
0814004	DELTA CER. INSERT	D. 40	GR.C
0814005	DELTA CER. INSERT	D. 40	GR. D
		1	1
		1	1
		İ	1
		İ	1
0893201	METAL INSERT	D. 32	GR.A
0893603	METAL INSERT	D. 36	GR. B
0894004	METAL INSERT	D. 40	GR.C
0894005	METAL INSERT	D. 40	GR. D
		1	•
0601020	D. 6.5 L. 20 mm	SCREW FOR CUP	
0601025	D. 6.5 L. 25 mm	SCREW FOR CUP	
0601030	D. 6.5 L. 30 mm	SCREW	FOR CUP
0601035	D. 6.5 L. 35 mm	SCREW	FOR CUP
0601040	D. 6.5 L. 40 mm	SCREW FOR CUP	
0601045	D. 6.5 L. 45 mm	SCREW FOR CUP	
0601050	D. 6.5 L. 50 mm	SCREW	FOR CUP

INSTRUMENT

		1	
IC00300	UNIVERSAL HANDLE		<u> </u>
IC04000 IC00800	TRIAL CUP HOLDER HANDLE CUP IMPACTOR	ł	
IC00804	PIN FOR IMPACTOR	1	+
IC07000	TOMMY BAR	1	
		1	1
IP34400	Size 44	Trial Cup	1
IP34600	Size 46	Trial Cup	1
IP34800	Size 48	Trial Cup	
IP35000	Size 50	Trial Cup	
IP35200	Size 52	Trial Cup	
P35400	Size 54	Trial Cup	
IP35600	Size 56	Trial Cup	
P35800	Size 58	Trial Cup	
IP36000	Size 60	Trial Cup	
P36200	Size 62	Trial Cup	
P36400	Size 64	Trial Cup	
P36600	Size 66	Trial Cup	
110400	D 28	159 TRIAL INCERT	
I10400 I30900	D. 28 D. 28	15° TRIAL INSERT	GR.A
130900 141200	D. 28 D. 28	15° TRIAL INSERT 15° TRIAL INSERT	GR. B GR. C
141200 151400	D. 28 D. 28	15° TRIAL INSERT	GR. D
131400 110500	D. 28	TRIAL INSERT	GR. A
I31000	D. 32 D. 32	TRIAL INSERT	GR. B
I41300	D. 32	TRIAL INSERT	GR. C
I41400	D. 40	TRIAL INSERT	GR. C
151500	D. 36	TRIAL INSERT	GR. D
151600	D. 40	TRIAL INSERT	GR. D
S01100	TIP GUIDE		1
S01200	HOLE MEASURING DEVICE		
S00900	FLEXIBLE SUPPORT		
S00901	FLEXIBLE TIP 30mm		
S00902	FLEXIBLE TIP 50mm		
S00600	FIXED TIP		
C00900	STANDARD SCREWDRIVER		
IS00500	CARDANIC SCREWDRIVER		
IS00700	PLIERS FOR SCREWS		
IC01000	FINAL IMPACTOR		
IC01100	D. 28	PE INSERT IMPACTOR	
IC01101	D. 32	PE INSERT IMPACTOR	
IC01102	D. 36	PE INSERT IMPACTOR	
IC01103	IMPACTOR HANDLE FOR PE INSERT	+	
1001105	INFACTOR HANDLE FOR FE INSERT	1	_
IC01300	D. 28	CERAMIC INSERT IMPACTOR	+
IC01401		CERAMIC INSERT IMPACTOR	
IC01402	D. 36	CERAMIC INSERT IMPACTOR	
IC01403	D. 40	CERAMIC INSERT IMPACTOR	
	İ		1
IC06801	EXTRACTOR FOR CERAMIC INSERT	GR.A	1
C06901	EXTRACTOR FOR CERAMIC INSERT	GR. B	
IC07001	EXTRACTOR FOR CERAMIC INSERT	GR. C	
IC07101	EXTRACTOR FOR CERAMIC INSERT	GR. D	
F10000	SET OF REAMERS		
F00100	REAMER FOR CUP	D. 42	1
F00200	REAMER FOR CUP	D. 44	<u> </u>
F00300	REAMER FOR CUP	D. 46	
		D. 48	
F00400	REAMER FOR CUP		
F00400 F00500	REAMER FOR CUP	D. 50	<u> </u>
F00400 F00500 F00600	REAMER FOR CUP REAMER FOR CUP	D. 52	
IF00400 IF00500 IF00600 IF00700	REAMER FOR CUP REAMER FOR CUP REAMER FOR CUP	D. 52 D. 54	
F00400 F00500 F00600 F00700 F00800	REAMER FOR CUP REAMER FOR CUP REAMER FOR CUP REAMER FOR CUP	D. 52 D. 54 D. 56	
F00400 F00500 F00600 F00700 F00800 F00900	REAMER FOR CUP REAMER FOR CUP REAMER FOR CUP REAMER FOR CUP REAMER FOR CUP	D. 52 D. 54 D. 56 D. 58	
F00400 F00500 F00600 F00700 F00800 F00900 F00900	REAMER FOR CUP REAMER FOR CUP REAMER FOR CUP REAMER FOR CUP REAMER FOR CUP REAMER FOR CUP	D. 52 D. 54 D. 56 D. 58 D. 60	
F00400 F00500 F00600 F00700 F00800 F00900 F01000 F01100	REAMER FOR CUP REAMER FOR CUP REAMER FOR CUP REAMER FOR CUP REAMER FOR CUP REAMER FOR CUP REAMER FOR CUP	D. 52 D. 54 D. 56 D. 58 D. 60 D. 62	
F00400 F00500 F00600 F00700 F00800 F00900 F01000 F01100 F01200	REAMER FOR CUP REAMER FOR CUP	D. 52 D. 54 D. 56 D. 58 D. 60 D. 62 D. 64	
F00400 F00500 F00600 F00700 F00900 F01000 F01100 F01200 F01300	REAMER FOR CUP REAMER FOR CUP	D. 52 D. 54 D. 56 D. 58 D. 60 D. 62 D. 64 D. 66	
F00400 IF00500 IF00600 IF00700 IF00800 IF00900 IF01000 IF01200 IF01300 IF01400	REAMER FOR CUP REAMER FOR CUP	D. 52 D. 54 D. 56 D. 58 D. 60 D. 62 D. 64 D. 66 D. 38 (Optional)	
F00400 F00500 F00600 F00700 F00800 F00900 F01000 F01100 F01200 F01300 F01400 F01500	REAMER FOR CUP REAMER FOR CUP	D. 52 D. 54 D. 56 D. 58 D. 60 D. 62 D. 64 D. 66	
IF00400 IF00500 IF00600 IF00700 IF00800 IF00900 IF01000 IF01200 IF01300	REAMER FOR CUP REAMER FOR CUP	D. 52 D. 54 D. 56 D. 58 D. 60 D. 62 D. 64 D. 66 D. 38 (Optional)	

Manufactured by Adler Ortho

CE 0426

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United Kingdom ADLER ORTHO UK

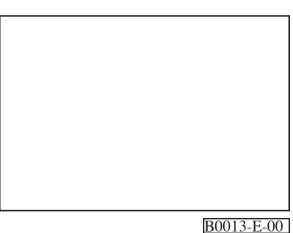
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Ti-Por[®] 07-2011





RECONSTRUCTIVE ORTHOPAEDICS



From project design to 3D prosthesis



Powder technology for custom made **3D prostheses**

A team of specialists working in close partnership with the surgeon

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Introducing a new web based custom process platform from Adler Ortho®; a company driven by innovation and highly experienced in the production of custom made 3D printed implants.



- 1) Web portal provides interactive link between the surgeon and Adler custom specialist team.
- 2) Processing, data exchange and 3D prototype visuals stored on portal.
- 3) Forms an archive for completed projects.



Adler Ortho® design platform for Custom-made 3D prosthesis production



CAT scan followed by established protocol and data communication

CAT protocol:

- Pixel size: 0.4
- Slice increment: 2 mm
- Width: 512
- Height: 512
- Orientation: RAB



Three-dimensional reconstructional control check

Three-dimensional reconstruction of the bone defect to be treated

DA

1) Trial implant validation 2) Drilling and instrument guide validation

Adler Ortho® guarantees the delivery of the implant and relative surgical instruments within 3 weeks of project validation by the surgeon

> Production of the Implant and its specific instruments

6



Creation of a 3D implant model according to the surgeon's instructions - Virtual solution

- Physical sample in ABS plastic

A journey in high technology. From project design to the 3D printed implant; the Adler team of custom implant specialists work in close collaboration with the surgeon

Perfect X-ray match between project design and final implant



Fixation versatility: "MODULAR" PRESS-FIT TECHNIQUE

A custom augment fills the bone defect and restores the integrity of the acetabular cavity. A conventional cup is then implanted in the reconstructed acetabulum

Courtesy of Dr. G. Burastero MIOS Albenga

Fixation versatility: **"PURE" PRESS-FIT TECHNIQUE**

When the type of defect permits, it is possible to use the press-fit technique to fix the custom implant like a first implant cup

Courtesy of Dr. G. Burastero MIOS Albenga



Image of the created custom implant

Three-dimensional reconstruction

Three-dimensional rendering of the implanted custom cup

Post-operative control

Fixation versatility: **BULK TECHNIQUE**

Acetabular reconstruction using a custom implant to completely fill defect

Courtesy of Dr. G. Giordano Toulouse



Construction of single-piece, three-dimensional, custom-made structures



- 70 year old patient

- Previously underwent two revisions of prior hip prostheses
- Septic loosening
- Paprosky IIIB defect



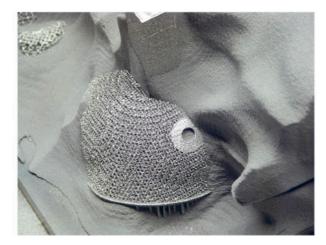
Trial implant

The implant is produced directly from titanium powder using an innovative production technique introduced for the first time in orthopaedics by Adler Ortho®.



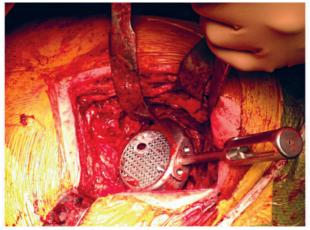


It is possible to produce single-piece three-dimensional structures, impossible to create with other methods.





Rear view of the custom implant designed to fill the bone defect completely



Intra-operative photo



Post-operative X-ray

Three-dimensional rendering of the implanted custom cup





- The custom implant is produced
- in a single piece.
- Powder technology makes it possible to modulate the three-dimensional structure of the implant with complete freedom, adapting it to the load and functional needs of the various areas.

Simple

Implants are modelled on the three-dimensional reconstruction of the patient's CT image.

Flexible

Powder technology permits the construction of even very complex structures adapting the implant to the anatomy of the patient, and not vice versa.



Safe

The implant is designed and produced in close collaboration with the surgeon. The procedure, controlled at every stage, also provides for the production of specific, disposable, surgical instruments to guarantee maximum precision during the intervention.





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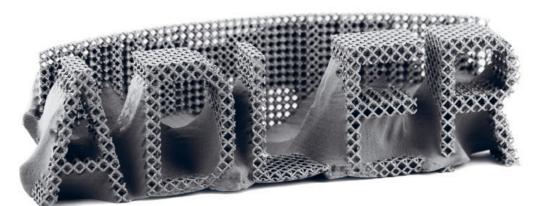
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Adler Ortho® design platform for the production of 3D custom prostheses

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