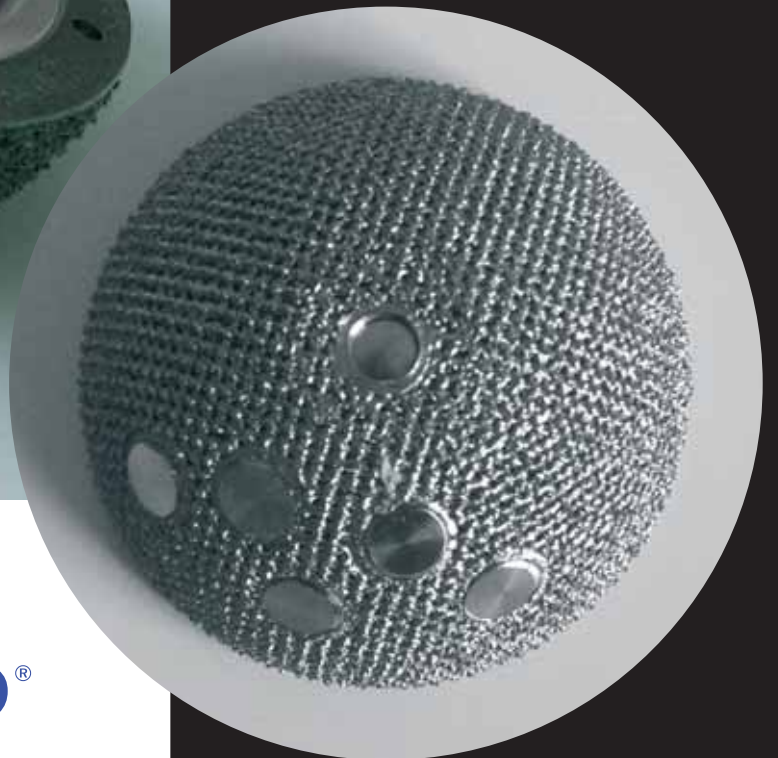




Cup Fixa



Cup Fixa



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

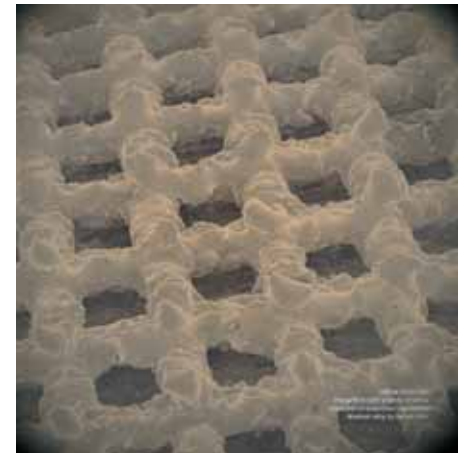
In addition to exploiting this safe mechanical concept which ensures primary fixation, the Fixa Ti-por cup is realized by means of a special and innovative production technique (Electron Beam Melting EBM) which makes it possible to obtain optimum porosity at the peripheral level, ideal for the trabecular 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”.



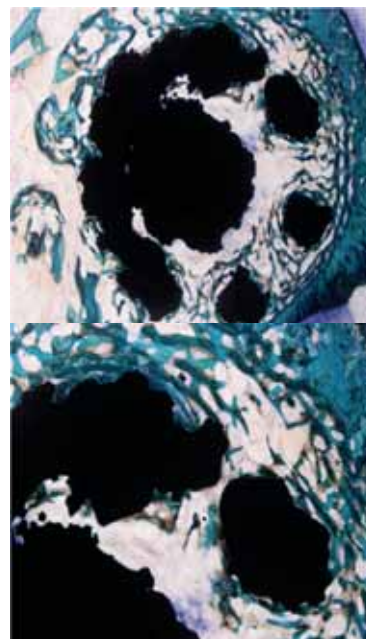
(A)

Pilot Study Conducted At The Laboratory of surgical pre-clinical 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

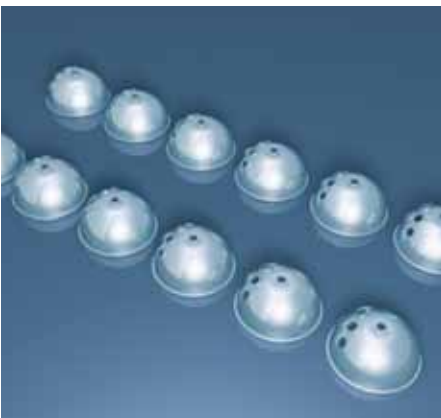


Two weeks from the surgery, spongy bone is observed in the repair phase with thin and dense trabeculae surrounding the implant and penetrating into the space created by the macroporosity of the biomaterial.

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.

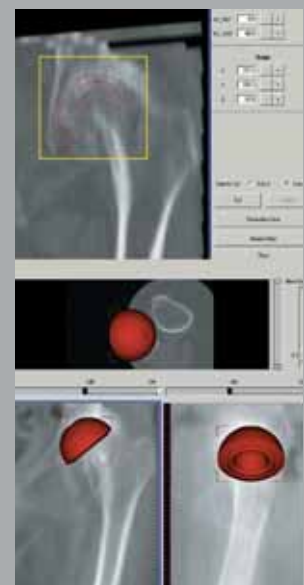
The ceramic insert fixing system consists of a conical fit on metal shell in order to ensure a tested mechanical grip.

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.

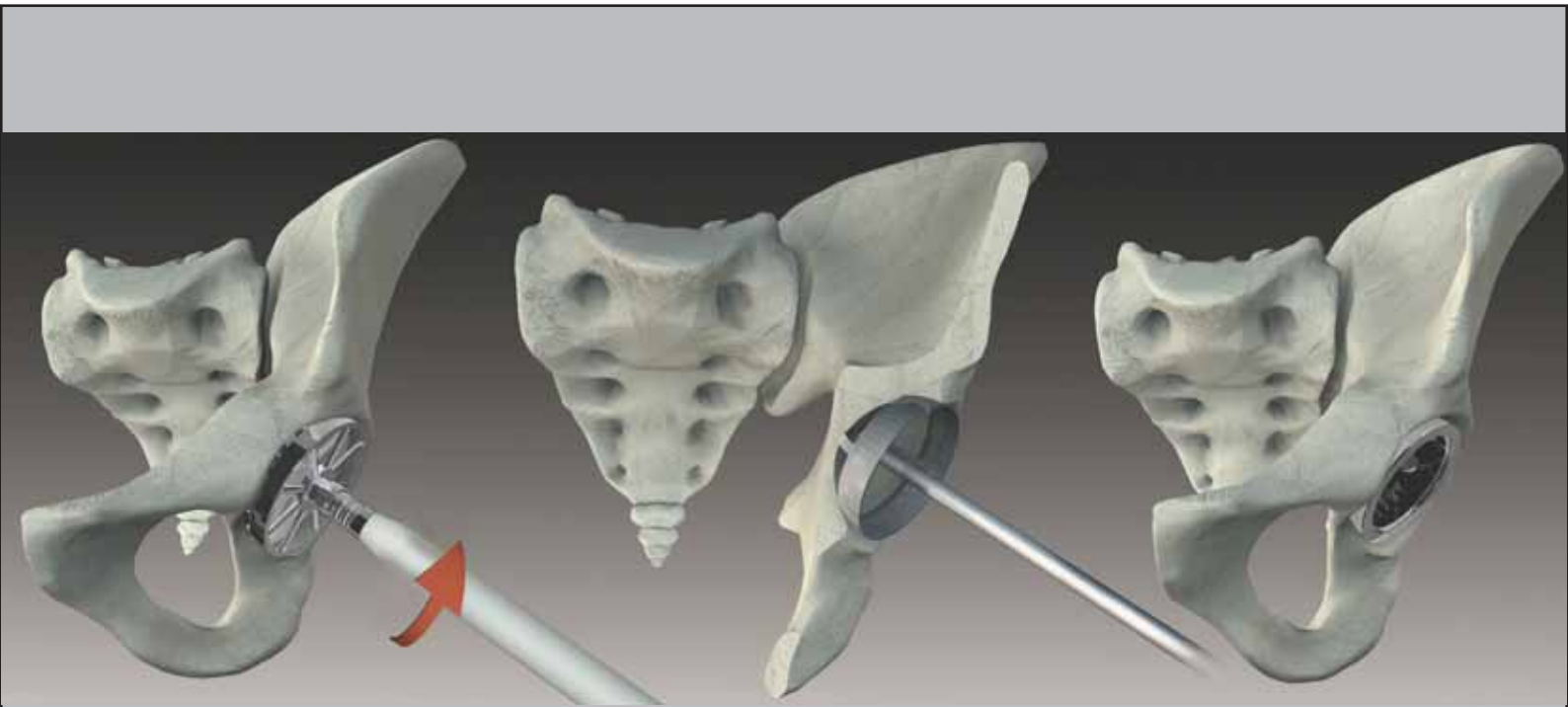
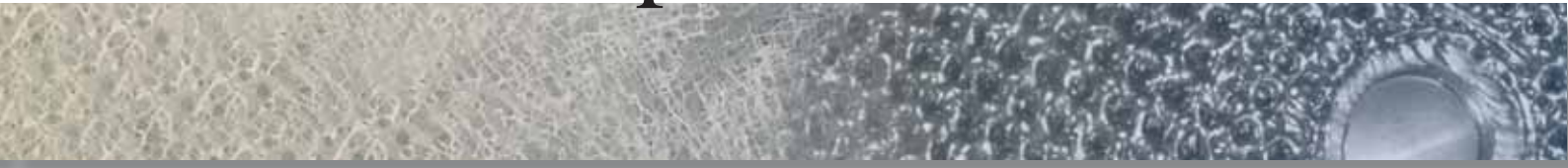


Surgical Study

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



Reaming the Acetabulum

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

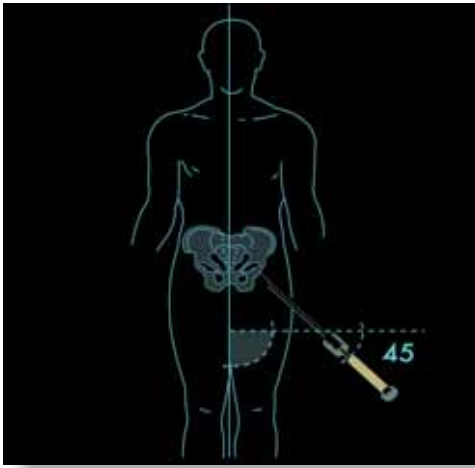
It is possible to start with reamers having smaller diameter, bearing in mind that it is not advisable to start with diameters excessively small-

ler than those of the acetabulum (except for dysplastic acetabulum, for which the use of reamers having small diameter is necessary to deepen the cavity in the direction of the paleocotyl).

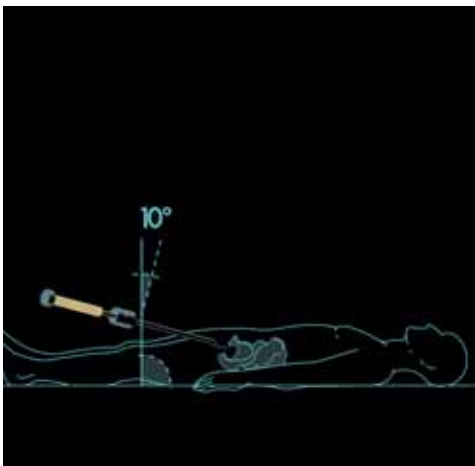
Proceed with the reamer having greater diameter to remove the fibrous or ivory-like tissue also on

the outermost surface of the acetabulum.

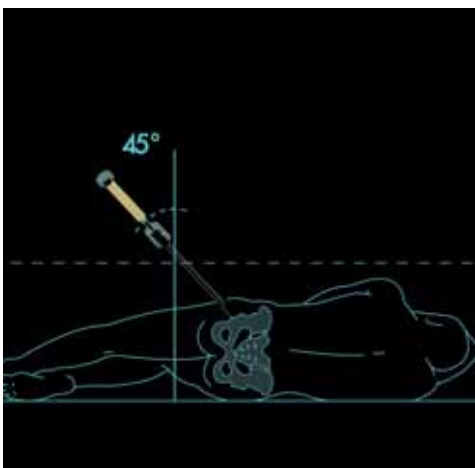
Then, just sink the reamer until it comes in contact with the acetabular bone covering.



1 Recumbent



2 Recumbent



On the side 1



On the side 2

TRIAL CUP

After the reaming proceed using the trial cup for checking to ensure uniform contact. To carry out this calibration correctly, use a trial cup size corresponding to the diameter of the last hemispheric reamer used. The final implant must correspond to the size of the trial cup which is best suitable for the prepared anatomic acetabulum.

NOTE: The FIXA Ti-Por cup has an equatorial diameter 1.5 mm more than the corresponding trial cup in order to ensure a perfect “press-fit”.

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.

Cup Fixa *Ti-POR*[®]



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

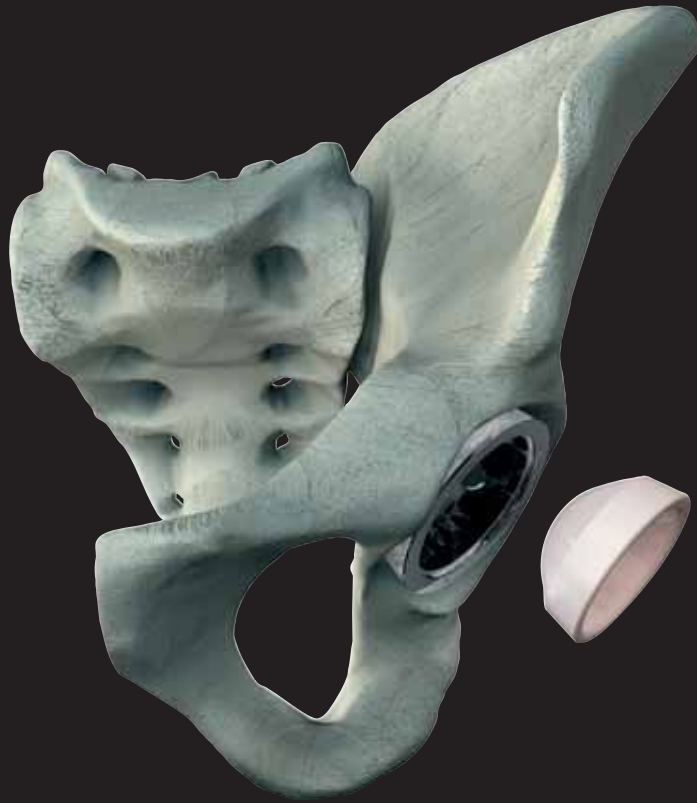
After selecting the insert to be implanted, after closing the apical hole by means of the screw provided, for the ceramic insert and metal insert, position this manually in the prosthetic cup and impact; for the polyethylene insert, use the special instrument provided for insertion.



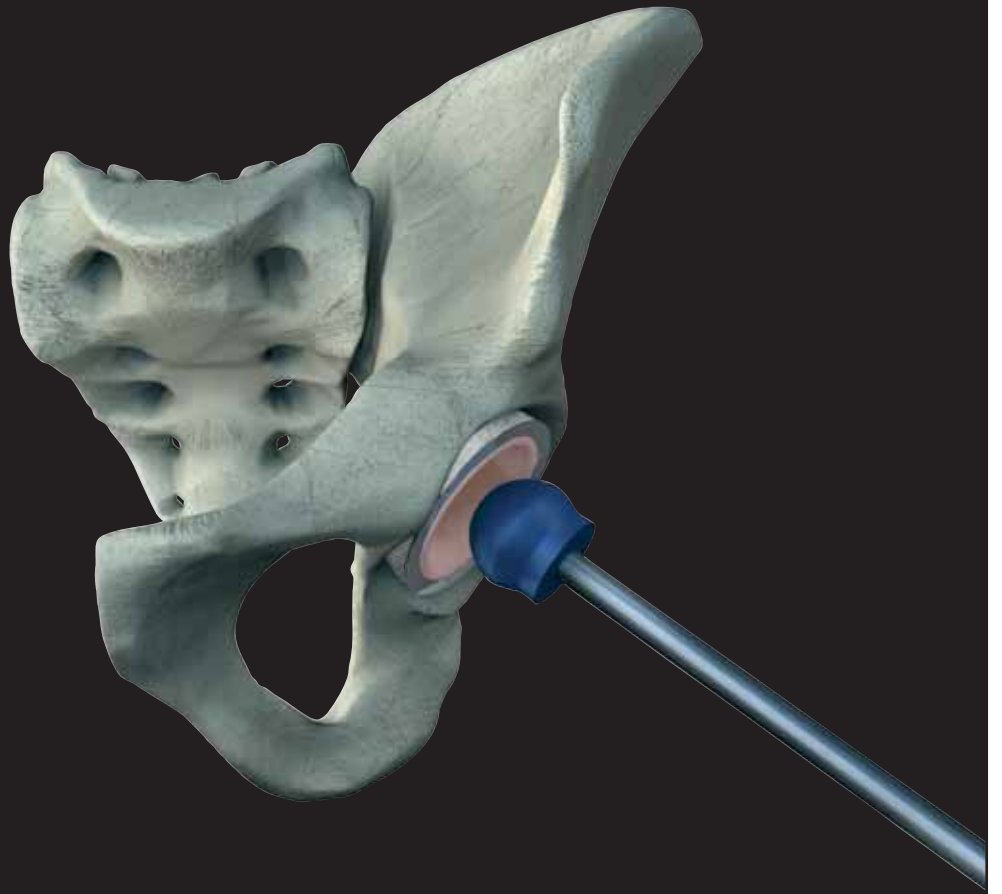
REMOVING THE CERAMIC AND/OR METAL INSERT

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  [®]



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
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
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
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
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

IC00300	UNIVERSAL HANDLE		
IC04000	TRIAL CUP HOLDER HANDLE		
IC00800	CUP IMPACTOR		
IC00804	PIN FOR IMPACTOR		
IC07000	TOMMY BAR		
IP14400	SIZE 44	TRIAL CUP	
IP14600	SIZE 46	TRIAL CUP	
IP14800	SIZE 48	TRIAL CUP	
IP15000	SIZE 50	TRIAL CUP	
IP15200	SIZE 52	TRIAL CUP	
IP15400	SIZE 54	TRIAL CUP	
IP15600	SIZE 56	TRIAL CUP	
IP15800	SIZE 58	TRIAL CUP	
IP16000	SIZE 60	TRIAL CUP	
IP16200	SIZE 62	TRIAL CUP	
IP16400	SIZE 64	TRIAL CUP	
IP16600	SIZE 66	TRIAL CUP	
II10400	D. 28	15° TRIAL INSERT	GR. A
II30900	D. 28	15° TRIAL INSERT	GR. B
II41200	D. 28	15° TRIAL INSERT	GR. C
II51400	D. 28	15° TRIAL INSERT	GR. D
III0500	D. 32	TRIAL INSERT	GR. A
II31000	D. 32	TRIAL INSERT	GR. B
II41300	D. 36	TRIAL INSERT	GR. C
II41400	D. 40	TRIAL INSERT	GR. C
II51500	D. 36	TRIAL INSERT	GR. D
II51600	D. 40	TRIAL INSERT	GR. D
IS01100	TIP GUIDE		
IS01200	HOLE MEASURING DEVICE		
IS00900	FLEXIBLE SUPPORT		
IS00901	FLEXIBLE TIP 30mm		
IS00902	FLEXIBLE TIP 50mm		
IS00600	FIXED TIP		
IC00900	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		
IC01300	D. 28	CERAMIC INSERT IMPACTOR	
IC01401	D. 32	CERAMIC INSERT IMPACTOR	
IC01402	D. 36	CERAMIC INSERT IMPACTOR	
IC01403	D. 40	CERAMIC INSERT IMPACTOR	
IC06801	EXTRACTOR FOR CERAMIC INSERT	GR. A	
IC06901	EXTRACTOR FOR CERAMIC INSERT	GR. B	
IC07001	EXTRACTOR FOR CERAMIC INSERT	GR. C	
IC07101	EXTRACTOR FOR CERAMIC INSERT	GR. D	
IF10000	SET OF REAMERS		
IF00100	REAMER FOR CUP	D. 42	
IF00200	REAMER FOR CUP	D. 44	
IF00300	REAMER FOR CUP	D. 46	
IF00400	REAMER FOR CUP	D. 48	
IF00500	REAMER FOR CUP	D. 50	
IF00600	REAMER FOR CUP	D. 52	
IF00700	REAMER FOR CUP	D. 54	
IF00800	REAMER FOR CUP	D. 56	
IF00900	REAMER FOR CUP	D. 58	
IF01000	REAMER FOR CUP	D. 60	
IF01100	REAMER FOR CUP	D. 62	
IF01200	REAMER FOR CUP	D. 64	
IF01300	REAMER FOR CUP	D. 66	
IF01400	REAMER FOR CUP	D. 38 (Optional)	
IF01500	REAMER FOR CUP	D. 40 (Optional)	
IF02000	UNIVERSAL REAMER-HOLDER		
IF03000	REAMERS STERILIZATION CONTAINER		

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Cup Fixa

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