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PROCOTYL™ E

Acetabular Cup System

Modular to Fit Patient's Anatomy. Versatile for Revisions.

PROCOTYL™ E Shell is a revision modular shell manufactured from titanium alloy.

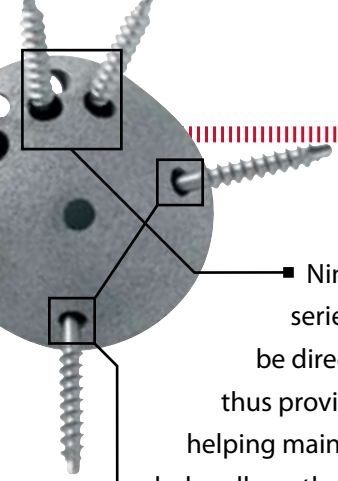
It is ovoid-shaped, with a 20° offset segment of the shell. The shell is designed specifically for particular revision cases, where migration and/or mobilization of cemented or uncemented prosthetic shells cause severe osteolysis in the acetabulum or generally in the pelvis. Osteolysis results in considerable modification of local anatomy. The acetabulum generally appears oblong, altered in its morphology cranially and/or caudally, antero-posteriorly and sometimes medially (protrusion), so as to make satisfactory use of hemispheric or similar primary shells extremely difficult.

The PROCOTYL™ E Shell may also be employed as a primary implant, when destruction or deformation are so severe that standard shells result in a poor fit, particularly in cases of revision arthrosis, dysplasia, and rheumatoid arthritis.

The design of this prosthetic component provides an effective answer to the need for reduction of polyethylene (PE) debris, which cause periprosthetic "osteolysis" in the acetabulum and femur.

In addition to PE coupling, the inner geometry of the PROCOTYL™ E Shell allows metal-on-metal coupling.

The outer shell surface features a 300 micron thick porous titanium coating, obtained through "PLASMA SPRAY" treatment, thus providing a better structure for bone rehabilition and a greater micro-porous surface to provide an optimal secondary osteointegration.



- Nine holes, disposed cranially in a double series, allow the use of fixation screws that can be directed to the iliac wing (5) and/or medially (4), thus providing primary stability of the implant and helping maintain bone grafts in situ. The shape of these holes allows the surgeon to select appropriate screw orientation (±10° approx.)

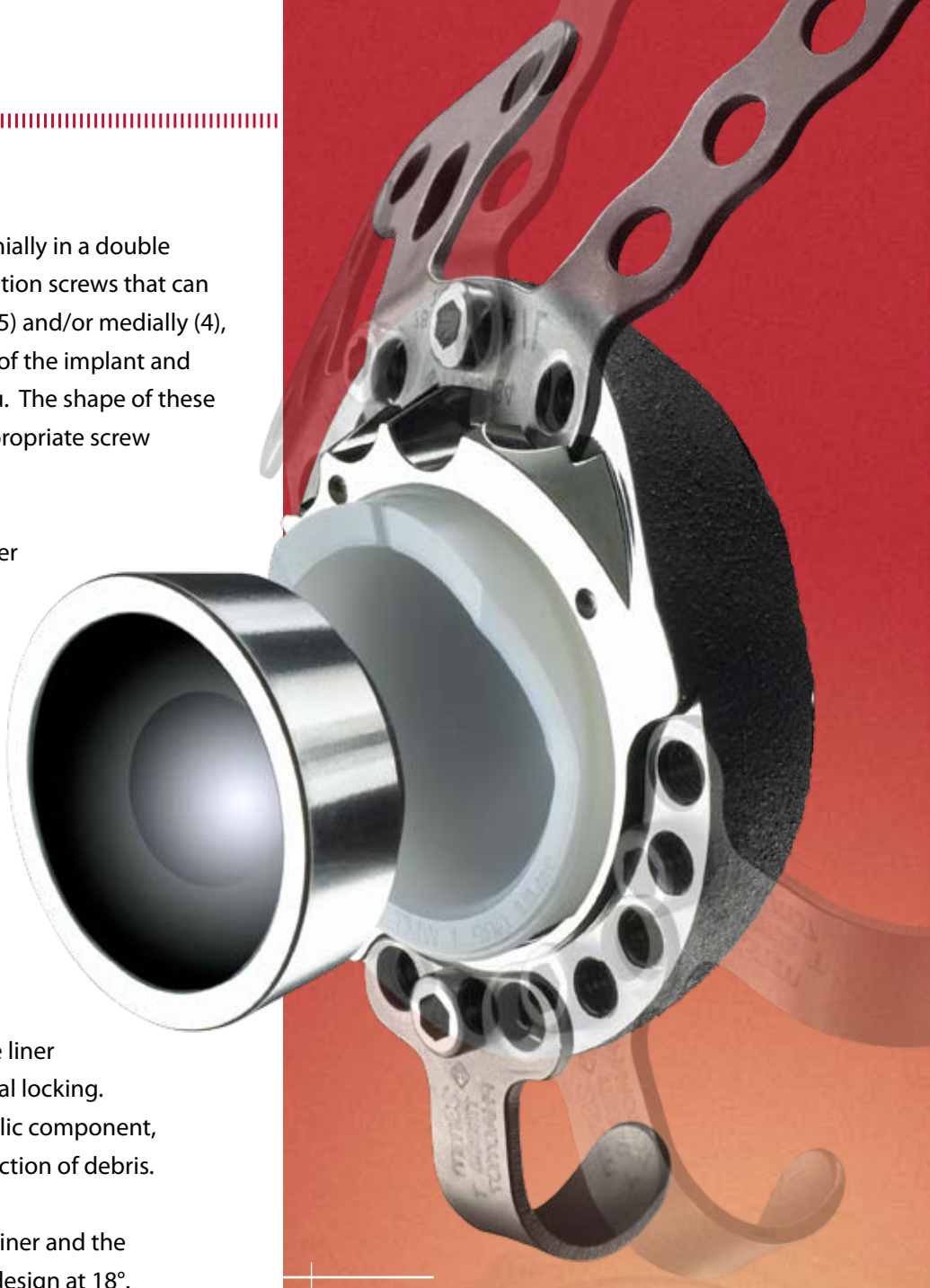
- Two additional holes located on the inner caudal zone of the shell allow the use of screws or pins that can be orientated towards the ischio-pubic wing, if required.

The PROCOTYL™ E Shell is available in 9 sizes, in 2mm intervals, each of which features a +8mm increment in the craniocaudal dimension with respect to antero-posterior dimension (e.g, A-P 60mm x C-C 68mm).

The coupling between the polyethylene liner and shell is achieved through mechanical locking. The liner has full-contact with the metallic component, thus minimizing the potential for production of debris.

The locking system between the metal liner and the PROCOTYL™ E Shell is trunco-conical in design at 18°.

Titanium alloy screws are available in 10 lengths (from 15 to 60mm), with a diameter of 5.5mm.



Thanks to its modularity, the PROCOTYL™ E Shell also allows use of a wide range of plates, hooks, 2nd blades, all of which are manufactured from titanium alloy and are available in various types and sizes, thus guaranteeing a stable and secure anchorage of the shell.

PROCOTYL™ E
acetabular cup system
SURGICAL TECHNIQUE

Proper surgical procedures and techniques are the responsibility of the medical professional. The following guidelines are furnished for information purposes only. Each surgeon must evaluate the appropriateness of the procedures based on his or her personal medical training and experience. Prior to use of the system, the surgeon should refer to the product package insert for complete warnings, precautions, indications, contraindications and adverse effects. Package inserts are also available by contacting Wright Medical Technology, Inc.

PRE-OPERATIVE PLANNING

Accurate pre-operative planning is a fundamental requisite in order to identify the size of the shell to use. It is conducted on a radiograph in standard projection (A/P) and with the aid of opportunely magnified templates (+15%).

The method is quite simple and consists of superimposing on the radiograph the PROCOTYL™ E Shell templates of the size and in the position deemed to be most suitable for the implant. On such templates the center of rotation is clearly indicated. Problems related to shell positioning may occur. A radiographic evaluation of the pelvis would, therefore, provide the possibility of a comparison with the contralateral joint.

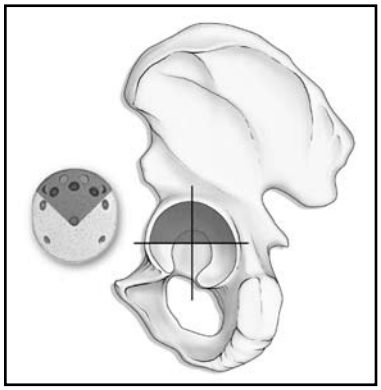


FIGURE 1 |

CENTER OF ROTATION

It is essential to identify the center of rotation of the prosthetic implant to be used. **| FIGURE 1** This can be obtained during the pre-operative planning, following these steps:

- **Position the shell template on the anatomic acetabulum (x-ray).**
- **Do not notch the cranial cortex.**
- **Do not position medially with respect to the radiographical tear-drop.**

It is then possible to draw the profile of the PROCOTYL™ E Shell to be implanted and to define the center of rotation.

Should the center of rotation thus obtained correspond to anatomical position, the surgeon can then proceed with the pre-operative study of the femoral implant (when required).

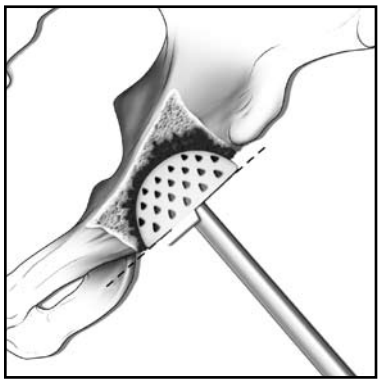
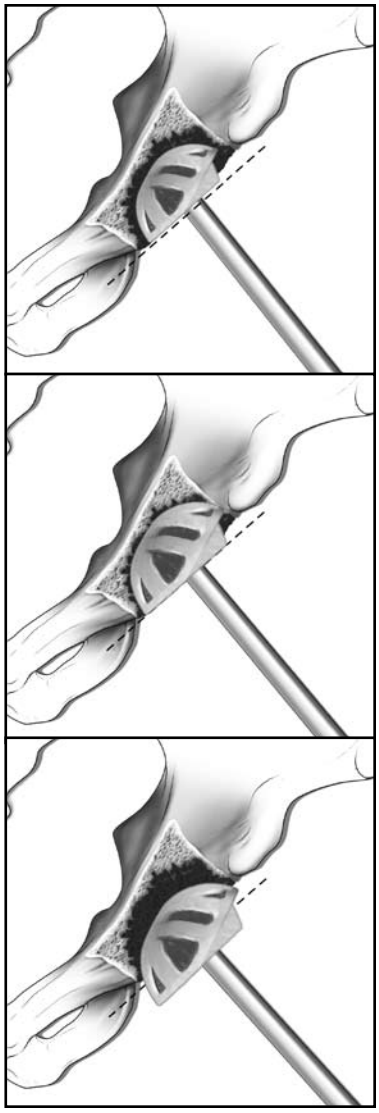


FIGURE 2 |

PREPARATION OF THE ACETABULUM

Once the acetabulum has been exposed, using the approach routinely preferred by the surgeon, the primary prosthetic shell, cement where applicable, debris and fibrous tissue is removed.

The preparation of the acetabulum continues with the use of spherical reamers with a diameter 4-6mm smaller than the implant size identified during pre-operative planning. **| FIGURE 2**



FIGURES 3A - 3C |
Determining optimal trial shell size

It is always advisable to preserve as much of the cranial region of the acetabulum as possible. Despite the recommendation, the surgeon should continue to ream until a good uniformity is achieved on the acetabular bone surface. Special care is required when positioning massive bone grafts or cancellous bone grafts, employed to improve inner wall strength and conformity. If necessary, bone compactors are available.

TRIAL SHELL

Once reaming is accomplished, trial shells can be used. It is possible to verify through the windows that the contact is as uniform as possible. Optimal assessment of the contact can be achieved by using PROCOTYL™ E Trial Shells corresponding to the nominal diameter of the last hemispheric reamer used, which in turn corresponds to the antero-posterior diameter of the shell.

It is always advisable to check stability with one size larger, even when the original trial shell appears well placed and secure.

Should the contact be poor, the different trail plates and/or hooks available may be added to provide an optimal fit and stability of the shell, paying special attention to the local bone structure where these devices are to be fixed.

NOTE | The definitive implant to be used must correspond to the size of the trial shell that best suits the prepared anatomical acetabulum.

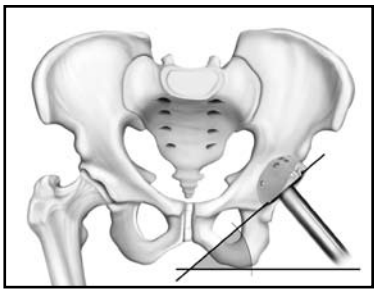


FIGURE 4 |

PROCOTYL™ E SHELL INSERTION

In order to position the PROCOTYL™ E Shell correctly, a lateral inclination of the shell between 40 ° and 45 ° and an ante-version between 10 ° and 15 ° is recommended. **| FIGURE 4** To help the surgeon achieve this orientation, the impactor includes angular guide rods.

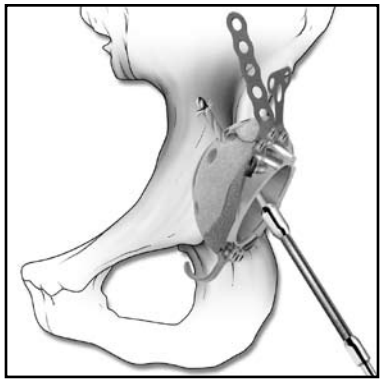


FIGURE 5 |

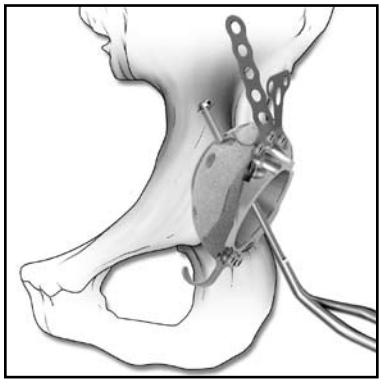


FIGURE 6 |

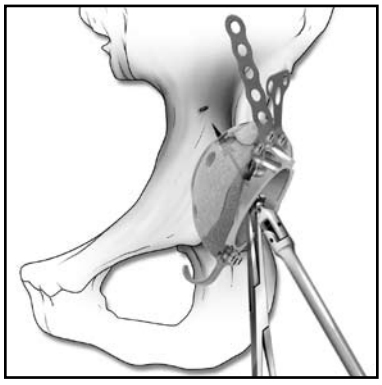


FIGURE 7 |

Once the orientation is verified, the shell is impacted into the acetabulum until covered by bone. The impactor is removed and the depth of sinkage is verified through the apical hole.

If there is still a little space between the acetabular floor and the shell, complete sinkage can be achieved with the aid of the final impactor.

Primary stability of the shell is obtained by "press-fit". However, should it be necessary, it is possible to increase primary stability with screws and the other modular fixation systems already tested on the trial shell.

If screws are required, their orientation and path should be prepared by means of the flexible drill bits. **| FIGURE 5** Determine the correct length of screw required using the depth gauge, and the screw may be held securely in place with the screw holding forceps. **| FIGURE 6** The screw is then carefully tightened into place using the flexible headed screwdriver. **| FIGURE 7**

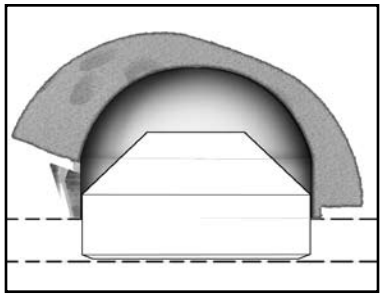


FIGURE 8 |

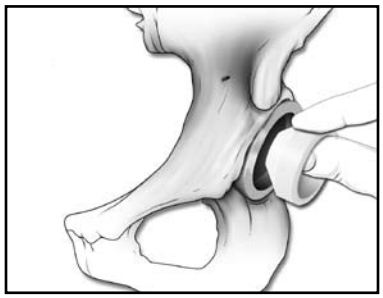


FIGURE 9 |

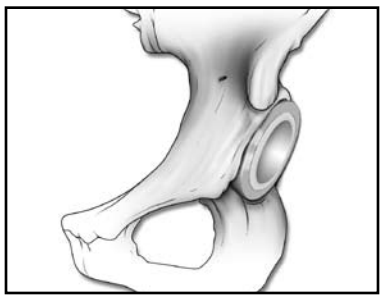


FIGURE 10 |

TRIAL LINER

The trial liner allows the surgeon to conduct a trial reduction and evaluate the final position of the PROCOTYL™ E Shell and articular geometry. The trial liner may be held securely in place by use of the pre-assembled screw through the apical hole of the PROCOTYL™ E Shell.

NOTE | PROCOTYL™ E Shells do not accept LINEAGE® Trial Liners. Use only the trial liners provided in the PROCOTYL™ E Instrument kit. **| FIGURE 8**

DEFINITIVE INSERT

Once the definitive liner is chosen, the surgeon should carefully wash and dry the internal surface of the shell and when selecting:

- a polyethylene liner, position by hand in to the prosthetic shell **| FIGURE 9** and then match the specific reference on the impactor with the slot on the liner and impact until the liner is fully secure. **| FIGURE 10**

- a metal liner, wash dry the liner and carefully position it into the prosthetic shell by hand **| FIGURE 9** and impact until the insert is secure. **| FIGURE 10** Select the size of impactor head relevant to the internal diameter of the chosen liner.

REMOVAL OF THE METAL LINER

Should it be necessary to remove the metal liner, the surgeon should use the specific extractors, taking care that the 4 pins coincide with the holes located on the equatorial plane of the prosthetic shell.

APPENDIX A | IMPLANTS

PROCOTYL™ E Acetabular Cup System Implants

CATALOG #	DESCRIPTION
PHA00370	SHELL SIZE 52/60 GROUP1
PHA00372	SHELL SIZE 54/62 GROUP1
PHA00374	SHELL SIZE 56/64 GROUP1
PHA00376	SHELL SIZE 58/66 GROUP2
PHA00378	SHELL SIZE 60/68 GROUP2
PHA00380	SHELL SIZE 62/70 GROUP2
PHA00382	SHELL SIZE 64/72 GROUP2
PHA00384	SHELL SIZE 66/74 GROUP3
PHA00386	SHELL SIZE 68/76 GROUP3
PHA01144	DOUBLE PLATE RIGHT - 4 HOLES
PHA01145	DOUBLE PLATE RIGHT - 5 HOLES
PHA01146	DOUBLE PLATE RIGHT - 6 HOLES
PHA01134	DOUBLE PLATE LEFT - 4 HOLES
PHA01135	DOUBLE PLATE LEFT - 5 HOLES
PHA01136	DOUBLE PLATE LEFT - 6 HOLES
PHA01106	HOOK - 18MM
PHA01107	HOOK - 23MM
PHA01108	HOOK - 28MM
PHA01112	"L" PLATE RIGHT - 5 HOLES
PHA01110	"L" PLATE LEFT - 5 HOLES
PHA01122	"T" PLATE RIGHT - 41.5MM
PHA01120	"T" PLATE LEFT - 41.5MM
PHA02915	SCREW - Ø =5.5MM L=15MM
PHA02920	SCREW - Ø =5.5MM L=20MM
PHA02925	SCREW - Ø =5.5MM L=25MM
PHA02930	SCREW - Ø =5.5MM L=30MM
PHA02935	SCREW - Ø =5.5MM L=35MM
PHA02940	SCREW - Ø =5.5MM L=40MM
PHA02945	SCREW - Ø =5.5MM L=45MM
PHA02950	SCREW - Ø =5.5MM L=50MM
PHA02955	SCREW - Ø =5.5MM L=55MM
PHA02960	SCREW - Ø =5.5MM L=60MM

LINEAGE® Acetabular Poly Liners — 28mm ID

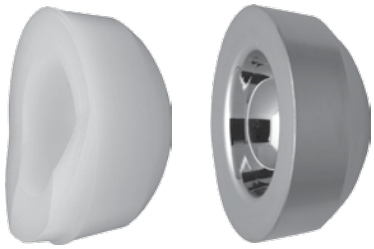
CATALOG #	DIMENSIONS
3645-2801	15° X 28MM - GROUP 1
3645-2802	15° X 28MM - GROUP 2
3645-2803	15° X 28MM - GROUP 3
3647-2801	15° X 28MM + 4 LAT - GROUP 1
3647-2802	15° X 28MM + 4 LAT - GROUP 2
3647-2803	15° X 28MM + 4 LAT - GROUP 3
3641-2801	0° X 28MM - GROUP 1
3641-2802	0° X 28MM - GROUP 2
3641-2803	0° X 28MM - GROUP 3
3643-2801	0° X 28MM + 4 LAT - GROUP 1
3643-2802	0° X 28MM + 4 LAT - GROUP 2
3643-2803	0° X 28MM + 4 LAT - GROUP 3

LINEAGE® Acetabular Poly Liners — 32mm ID

CATALOG #	DIMENSIONS
3645-3202	15° X 32MM - GROUP 2
3645-3203	15° X 32MM - GROUP 3
3647-3202	15° X 32MM + 4 LAT - GROUP 2
3647-3203	15° X 32MM + 4 LAT - GROUP 3
3641-3202	0° X 32MM - GROUP 2
3641-3203	0° X 32MM - GROUP 3
3643-3202	0° X 32MM + 4 LAT - GROUP 2
3643-3203	0° X 32MM + 4 LAT - GROUP 3

LINEAGE® Acetabular Metal Liners

7010-2846	28MM ID - GROUP 1
7020-3252	32MM ID - GROUP 2
7030-3258	32MM ID - GROUP 3



APPENDIX B | INSTRUMENTATION

PROCOTYL™ E Instrumentation Kit #8000 Kit 5

CATALOG #	DESCRIPTION
PPR68016	FLEXIBLE DRILL Ø=3.2MM L=55MM
PPR68014	FLEXIBLE DRILL Ø=3.2MM L=35MM
APA04560	DRILL GUIDE Ø =3.2MM
APA05852	TRIAL LINER 18°
	28MM X 37MM - GROUP 1
APA05856	TRIAL LINER 18°
	28MM X 41MM - GROUP 2
APA05860	TRIAL LINER 18°
	28MM X 48MM - GROUP 3
APA05858	TRIAL LINER 18°
	32MM X 41MM - GROUP 2
APA05862	TRIAL LINER 18°
	32MM X 48MM - GROUP 3
PPR68020	SCREW DEPTH GAUGE
PPR68018	SCREW HOLDER
APA05151	HANDLE FOR TRIAL SHELLS, COMPACTORS, AND CAP IMPACTORS
APA05102	METAL LINER EXTRACTOR - GROUP 1
APA05104	METAL LINER EXTRACTOR - GROUP 2
APA05106	METAL LINER EXTRACTOR - GROUP 3
APA01584	PLATE AND HOOK HOLDER
APA05111	PLATE BENDER
80003200	TRANSCEND LINER POSITIONER
80002800	TRANSCEND LINER POSITIONER
80003215	LINEAGE LINER POSITIONER
80002815	LINEAGE LINER POSITIONER
80000010	TRANSCEND INSERT IMPACTOR
80000020	TRANSCEND MODULAR LINER
APA05152	CUP IMPACTOR
APA05112	TRIAL SHELL S.52MM X 60MM
APA05114	TRIAL SHELL S.54MM X 62MM
APA05116	TRIAL SHELL S.56MM X 64MM
APA05118	TRIAL SHELL S.58MM X 66MM
APA05120	TRIAL SHELL S.60MM X 68MM
APA05122	TRIAL SHELL S.62MM X 70MM
APA05124	TRIAL SHELL S.64MM X 72MM
APA05126	TRIAL SHELL S.66MM X 74MM
APA05128	TRIAL SHELL S.68MM X 76MM
APA05132	COMPACTOR Ø=52MM
APA05134	COMPACTOR Ø=60MM
APA05136	COMPACTOR Ø=66MM
APA05140	SIZER
APA05142	HEXAGONAL SCREWDRIVER 3.5MM
APA01534	DOUBLE PLATE TRIAL - 4 HOLES
APA01535	DOUBLE PLATE TRIAL - 5 HOLES
APA01536	DOUBLE PLATE TRIAL - 6 HOLES
APA01520	"T" PLATE TRIAL
APA01510	"L" PLATE TRIAL
APA01592	TRIAL HOOK L=18MM
APA01594	TRIAL HOOK L=23MM
APA01596	TRIAL HOOK L=28MM
APA05144	ILIAC LOCKING PLATE
APA05143	HOOK LOCKING PLATE
APA05150	CARDAN SCREWDRIVER 3.5MM

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