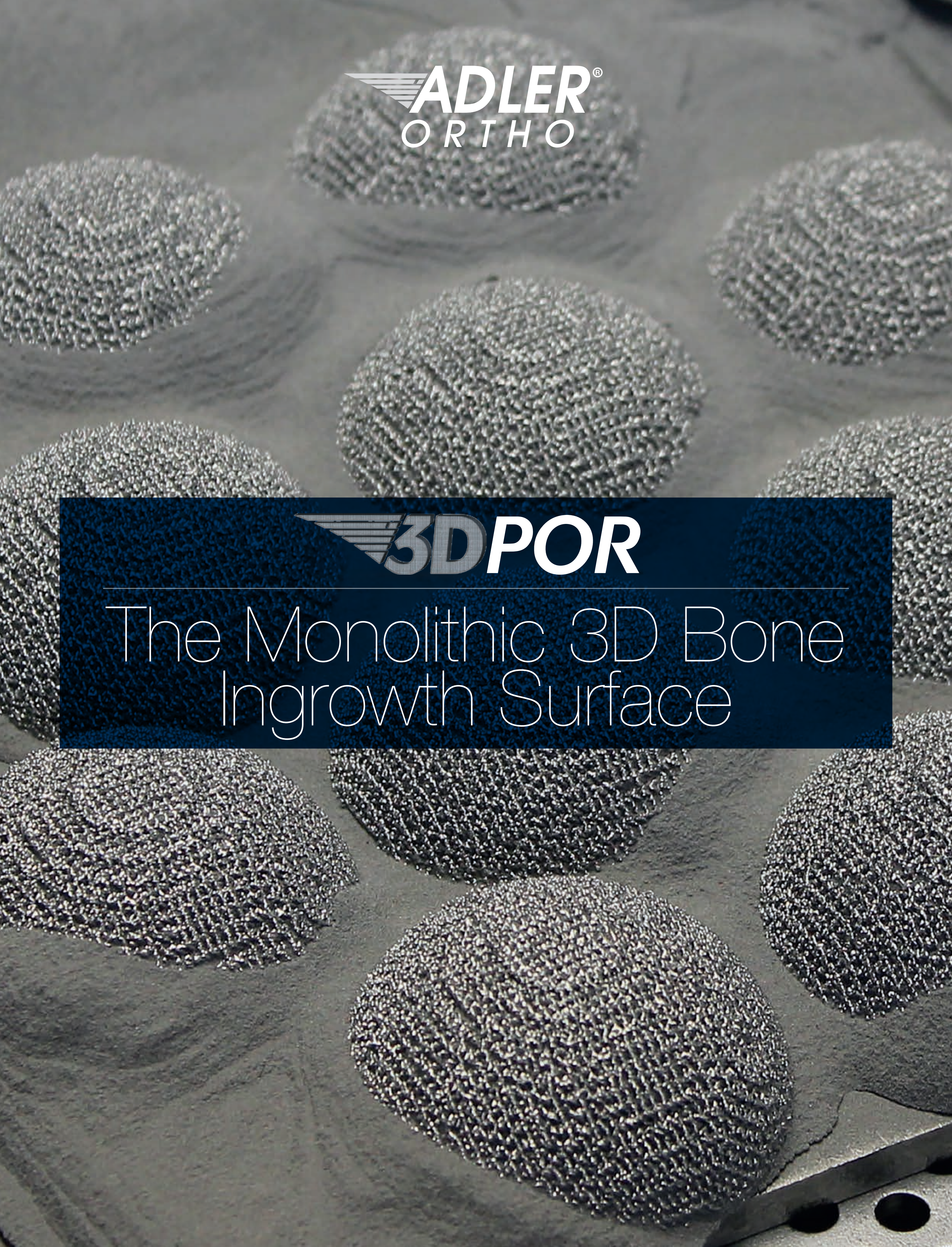


ADLER® ORTHO

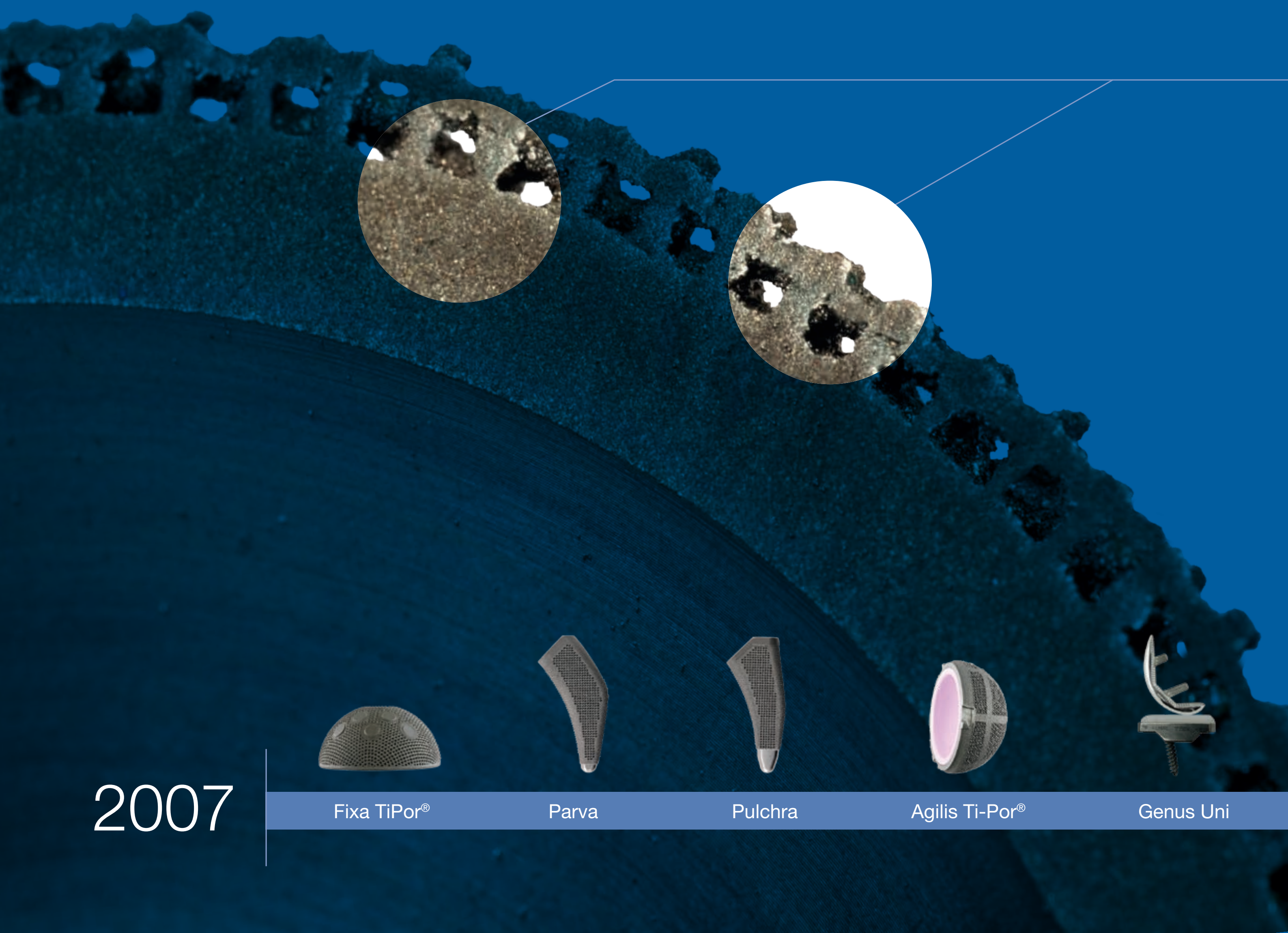
3DPOR

The Monolithic 3D Bone Ingrowth Surface

Powder Manufacturing Technology

Implants are produced directly from a CAD model using metal powder without employing any traditional physical tool. The implant is built by adding layer over layer of material to create a solid structure, ready for final finishing.

This technology allows manufacturing of complex **monolithic three-dimensional metal structures** otherwise impossible to make.
It is therefore possible to manufacture cementless implants with very rough monolithic surfaces and interconnected three-dimensional porosity, ideal to maximize primary stability and promote the subsequent **osseointegration**.

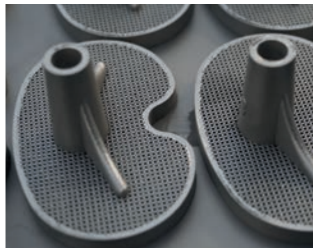


Powder Technology and Orthopaedic Implants

Adler Ortho® were the first company to adopt Powder Manufacturing Technology for orthopaedic implant mass production.

Today Adler Ortho® provides Orthopaedic Surgeons with the broadest portfolio of Powder Manufactured Implants and instruments in the Industry utilizing all the typical metal alloys such as Titanium, Cobalt Chrome and Stainless Steel.

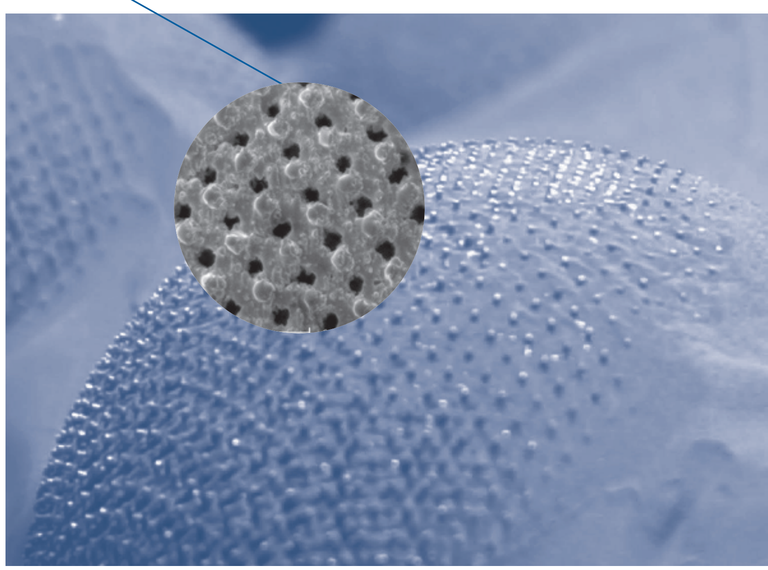
In 2017 Adler Ortho® opened a new state of the art fully automated factory completely devoted to Powder Manufacturing Technology for Orthopaedic Implants and instruments.

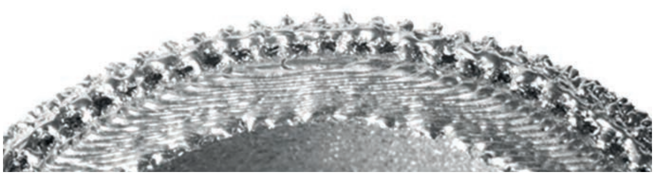


3DPOR Surface

The 3D-Por® surface represents the main achievement of Adler Ortho® research in the field of additive manufacturing and Orthopaedic Implants.

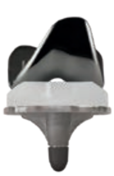
3D-Por® is a three-dimensional monolithic surface with interconnected pores (average porosity 700 μm) and 0.4mm high spikes designed to enhance surface roughness. The 3D-Por® surface can be manufactured both in Titanium alloy as well as in CoCrMo alloy. The former surface is then called **Ti-Por®**, while the latter is called **Co-Por®**.





A section of the Ti-Por® surface.
The 0.4mm high monolithic spikes are designed to maximize implant primary stability.

PolyMax Ti-Por®



Genus MB-FB

Fixa Duplex

Custom made

Antea

3DPOR

The Product Range

After the launch of the Fixa Ti-Por® cup in 2007, the first powder manufactured implant in the world, the 3D-Por® surface has been the foundation for the design of a broad portfolio of orthopaedic implants including hip, knee, custom-made and extremities.

To date more than 100,000 implants featuring the 3D-Por® surface have been implanted worldwide.

Hip

The 3D-Por® surface is integrated in the design of a full range of primary and revision acetabular components both modular and pre assembled, and of modular or monolithic MIS hip stems.
Adler Ortho® offers a unique product: the CoCrMo made Fixa Duplex dual mobility cup, featuring the Co-Por® surface.

Knee

Adler Ortho® Cementless fixed bearing Unicompartmental as well as Total Knee tibial components feature the Ti-Por® surface. The femoral components feature the Co-Por® Surface, which is the CoCrMo alloy equivalent of Ti-Por®.

Custom Implants

Adler Ortho® has a very successful line of Custom Made implants that are mainly used for joint reconstruction or oncology applications. Implants are designed to precisely match the patients anatomy, derived from CT and / or MRI scans. The Ti-Por® surface enhances primary stability and promotes rapid osseointegration.

Extremities

Ti-Por® technology has recently been used to develop Extremities implants with the introduction of the Antea modular radial head prosthesis. The powder manufactured radial stem features the Ti-Por® surface to maximize implant stability.

Ti-Por®
Mechanical Tests(*)

Traction resistance **test** according to ASTM F1147-05

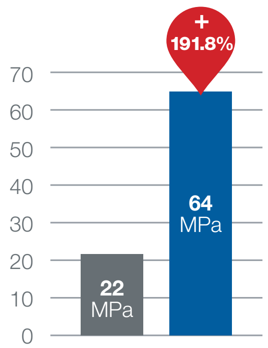
Minimal resistance accepted by the Standard: 22MPa

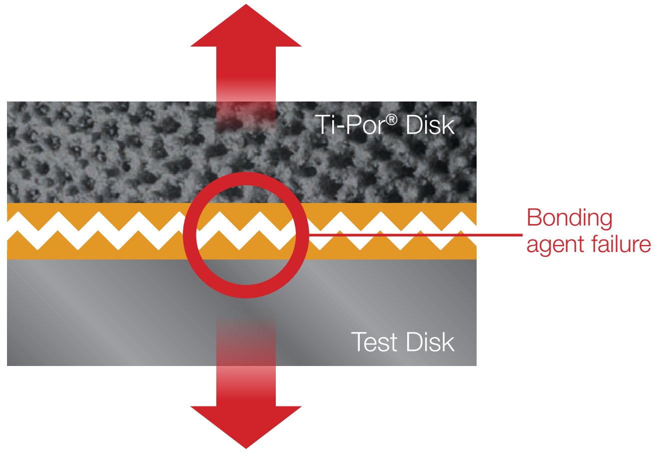
Results
No sign of detachment or damage was observed on the Ti-Por® Surface.

Detachment of the two disks eventually occurs due to bonding agent failure.

Minimum resistance accepted by ASTM

Ti-Por® Result





Shear resistance **test** according to ASTM F1144-05

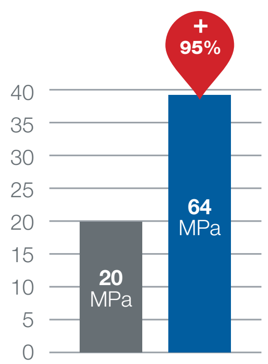
Minimum resistance accepted by the Standard: 20MPa

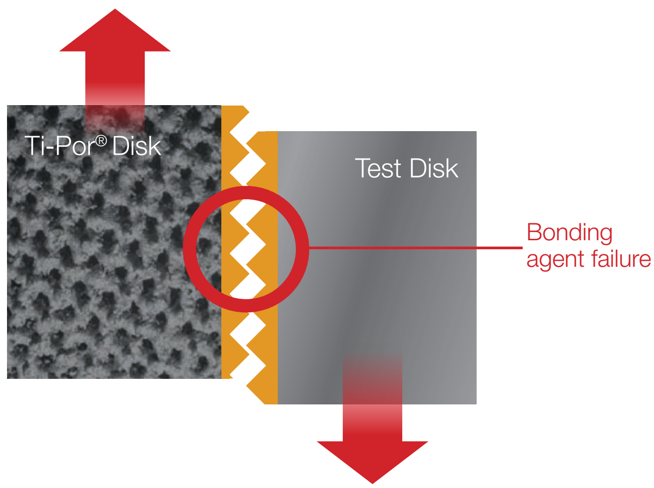
Results
No sign of detachment or damage was observed on the Ti-Por® Surface.

Detachment of the two disks eventually occurs due to bonding agent failure.

Minimum resistance accepted by ASTM

Ti-Por® Result





Deformation test

A series of Fixa Ti-Por® cups were submitted to gradually increasing vertical compression load until reaching a permanent deformation flattening the cup dome.

Results
Powder Manufactured implants demonstrated a high resistance to deformation. Even in case of extreme deformation no detachment of the Ti-Por® surface was observed.

Fixa Ti-Por® cup before and after deformation test

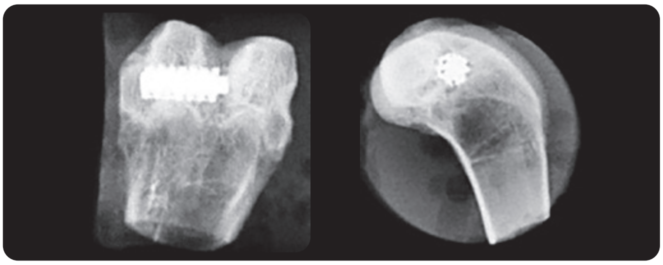
The Ti-Por® deformation test demonstrates that it is impossible to detach from its substrate under any stress or deformation pressure.

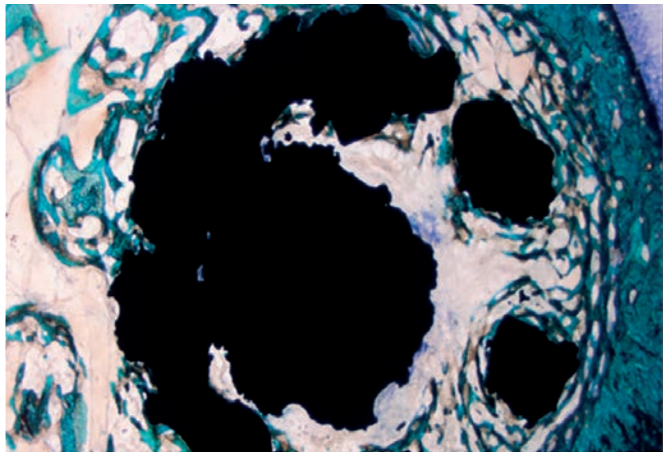
(*) Data available on file at Adler Ortho®

Ti-Por®
Bone integration in-vivo tests(*)

Fast Bone integration

Ti-Por® cylinders inserted into adult rabbits distal femurs showed clear signs of bone integration at **2 weeks** after implantation.

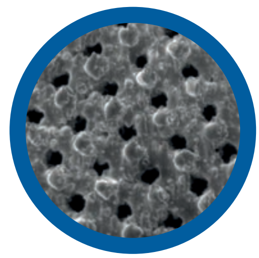




Strong and reliable osseointegration

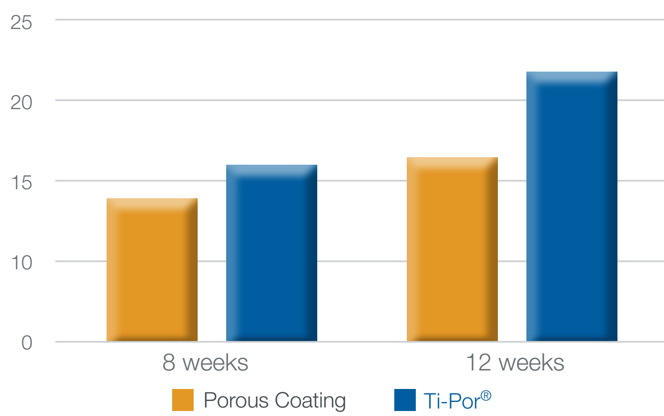
Ti-Por® and standard porous coating cylinders were implanted in adult rabbits distal femurs.

Osseointegration strength was measured employing a push-out test method trying to mobilize matched pairs of Ti-Por® and porous coating cylinders 8 weeks and then 12 weeks after surgery.



Results

- **8 weeks after implantation** Ti-Por® and porous coated cylinders show similar resistance to push out.
- **12 weeks after implantation** Porous coated cylinders resistance to push-out remained nearly unchanged, while resistance of Ti-Por® cylinders showed an increase of 32%.



Conclusions

12 weeks after implantation Ti-Por® showed a superior osseointegration strength vs porous coating.

This result could be attributed to a better vascularization and maturation of the newly formed bone allowed by the Ti-Por® 3D interconnected structure.

Ti-Por® osseointegration was so strong that in many cases attempts to completely push out the cylinders resulted in fracture of the bone, whilst porous coated cylinders were pushed directly out without fracture.

Results of Porous cylinders push-out.

Results of Ti-Por® push-out. Bone was fractured around the cylinder.

(*) Data available on file at Adler Ortho®

3DPOR
Clinical Results

A case treated with an entirely powder manufactured hip implant (Fixa Ti-Por® cup and Parva stem).
X-Ray at 8 years Follow-up.
Clear signs of stable and reliable osseointegration.
(Courtesy of Dr. Marco Schiraldi)

Survival data on a cohort of 152 consecutive Parva Stems with Fixa Ti-Por® cup.

Minmum follow-up 43 months.
Maximum follow-up 72 months (*)

99.3%

Survival at **5 years**
With revision of any component as end point

0.0%

Failures because of aseptic loosening

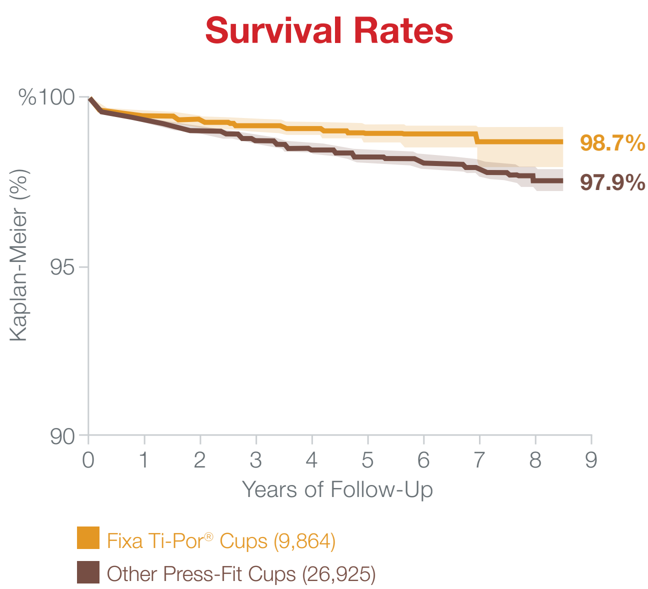
Conclusion

"The current study has shown that implantation of the Parva stem leads to good clinical and radiographic outcome after a mean follow-up of 56 months."

(*) M. Schiraldi, M. Bondi, L. Renzi Brivio (2019) Femoral neck preservation with a short hip stem produced with powder manufacturing: mid-term results of a consecutive case series. EJOST 2019 Jan 28 doi: 10.1007/s00590-019-02381-y.

Survival data on a cohort of 9,864 Fixa Ti-Por® cups compared with other press-fit cups (26,925 implants) included in the RIPO Joint Registry(**)

Fixa Ti-Por® Cup



Conclusion

"The use of a highly porous titanium cup, as Fixa Ti-Por®, seems effective when compared to currently adopted cups, with a notable reduction of revisions due to aseptic loosening."

(**) F. Castagnini and Others (2018).
Highly porous titanium cup in cementless total hip arthroplasty: registry results at eight years. International Orthopaedics 2018 Aug 23. doi: 10.1007/s00264-018-4102-9.

ODEP 10A*

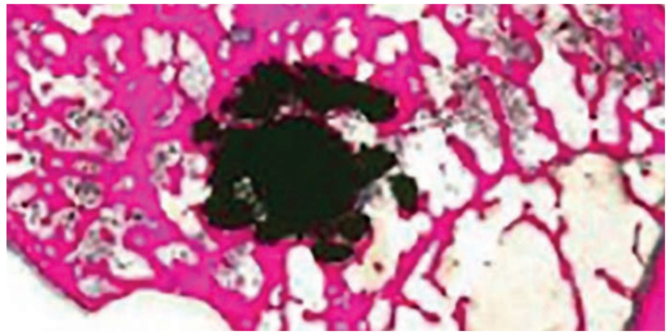
ODEP (Orthopaedic Devices Evaluation Panel) Rating Granted to the Fixa Ti-Por® Cup (www.odep.org.uk)

Co-Por®
Bone integration in-vivo tests(*)

Strong and Reliable Osseointegration

Cylinders with three different surfaces: Co-Por®+ HA; Porous beads coating + HA and Ti Plasma Spray + HA had been implanted with a line to line technique in adult rabbits distal femoral condyles according to UNI EN ISO 10993-6:2009.

Signs of new bone formation, and bone maturation were checked 4 weeks and 12 weeks after surgery.



Results

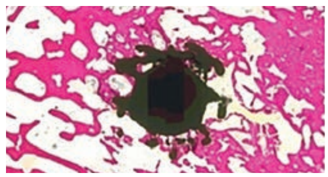
Co-Por®+ HA Specimen 4 and 12 weeks post-op at various degrees of magnification.

The black arrows on pictures C (yellow/green colours) show osteoblasts activity with deposition of newly formed bone.

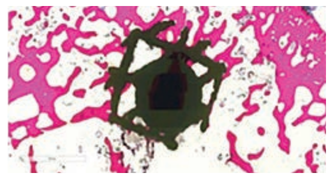
Picture D shows the direct contact between the implant and newly formed bone without any fibrous tissue interposition.

4 Weeks

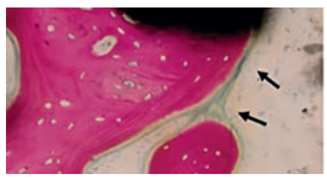
12 Weeks



A 1.4X Magnifications



B 1.4X Magnifications



C 40X Magnifications

D 20X Magnifications

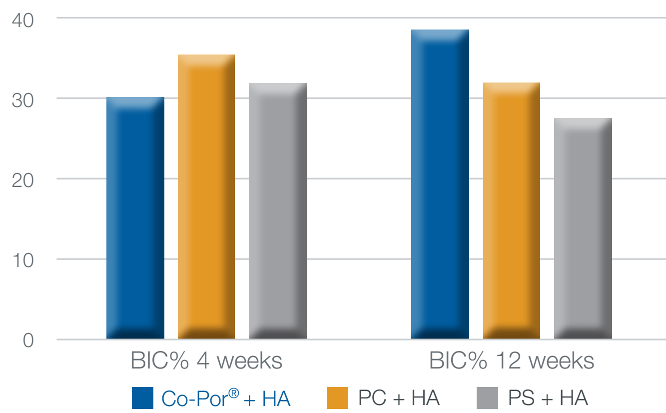
Bone to Implant Contact (BIC%)

BIC% higher values are indicative of a higher % of the implant surface in contact with bone.

Results

- **4 weeks after surgery Co-Por® + HA** specimens showed a BIC% index comparable to Porous Beads coating and Plasma Spay.
- **12 weeks after surgery Co-Por®** specimens BIC% index grew almost a further 30% whilst the other specimens both declined in surface contact with bone.

Co-Por® + HA vs Porous Beads Coating and Ti Plasma Spray



Conclusions

Co-Por® + HA seems to have a better Bone to Implant contact ratio vs other ingrowth surfaces taken as reference.

(*) Data available on file at Adler Ortho®

ADLER ORTHO

ADLER ORTHO

Headquarters
ADLER ORTHO® S.p.a.
Via Dell'Innovazione, 9
20032 Cormano (Mi)
Tel. +39 02 6154371
Fax +39 02 615437222
Mail: info@adlerortho.com

Sedi:
Bologna
Via Guelfa, 9
Tel. +39 051 533266
Fax. +39 051 538772

Verona
Via Pacinotti, 4B
Tel. +39 045 8230327
Fax. +39 051 8230660

Roma
Via delle Benedettine 86
Tel. +39 06 30600445
Fax. +39 06 30601361

Belgium:
ADLER ORTHO®
Business Park Berbroek
Steenweg 3, Unit 701
3540 Herk De Stad (Belgium)
Tel. +32 2 3433340
Fax +32 2 3433380
www.belgafix.be

France:
ADLER ORTHO® France SAS
Arteparc
Bâtiment F
Route de la côte d'azur
13590 Meyreuil Le Canet
Tel. +33 (0) 4 42 90 07 53
Fax +33 (0) 4 42 90 68 84

Germany:
ADLER ORTHO®
Deutschland GmbH
Am Hag 16
D-36369 Lautertal, Deutschland
Tel. +49 (0) 6643 799488
Fax +49 (0) 6643 799466
Mail: info@adlerortho.de
Amtsgericht Köln HRB 83961

Suisse SA
Via Balestra, 33
Lugano (Svizzera)
Tel. +41 78 401 4779
Fax +41 91 605 7790

United Kingdom:
Adler Ortho UK Ltd
The Stables
Tarvin Road
Frodsham - Cheshire -
WA6 6XN
Tel. +44 (0) 151 329 3372
Mail: info@adlerorthouk.com

Japan:
Adler Ortho Japan
4F, Rinyu-Build., 1-7-12,
Kouraku, Bunkyo-ku,
Tokyo 112-0004
Tel. +81-3-5801-0913
Fax. +81-3-5801-0915
Mail:
information@adlerjapan.co.jp

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