X-PS®

PS®

LorX® ACIF

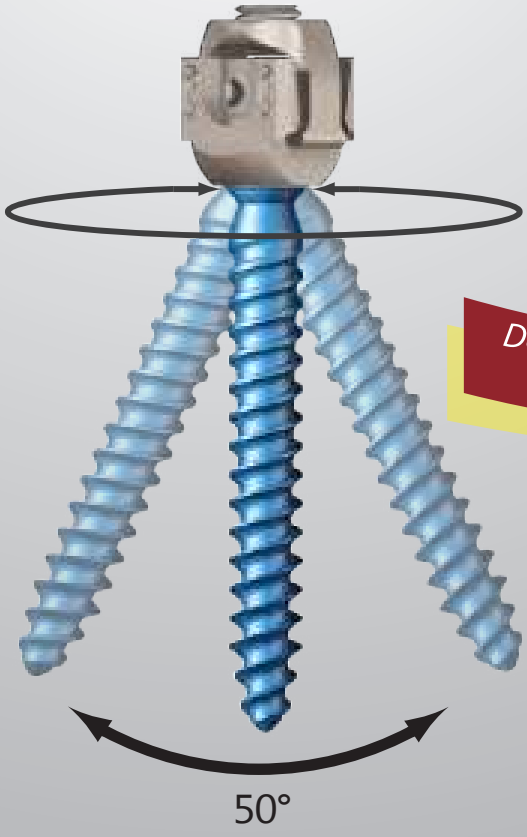
LorX® PLIF

LorX® TLIF

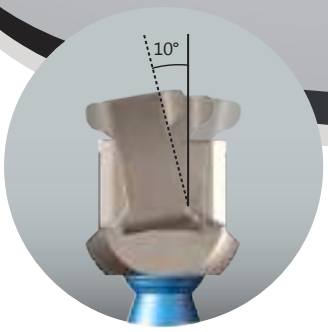
Tria Spine®

...evolution of spine

# X-PS®
## thoraco-lumbar system

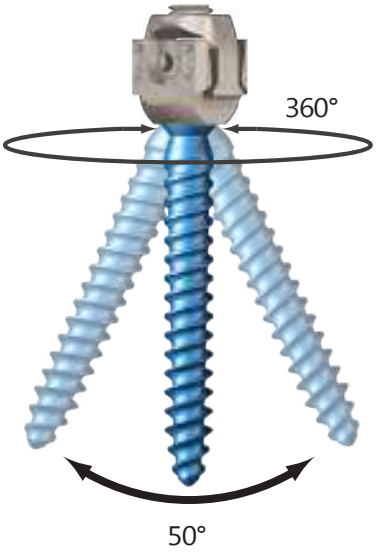



Double Threaded




Tria Spine®

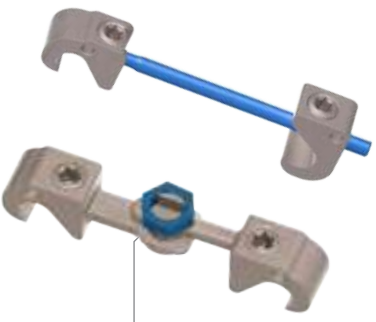
...evolution of spine




**6mm rod system**
6mm rod system for stronger constructs and universal use


**Variation of 70°**
Provides a variation of 70° in angle in total for best anatomic position

**Screw tip**
Improved screw tip for easy insertion



**Adjustable cross links**
Adjustable cross links for every construct in 4 sizes between 30mm and 70mm

**- Mono-Axial Screw**
- Diameter : 4.0mm to 8.0mm
- Length : 25mm to 60mm

**- Multi-Axial Screw**
- Diameter : 4.0mm to 8.0mm
- Length : 25mm to 60mm

**- Multi-Axial Cement Type Screw**
- Diameter : 5.5mm and 6.5mm
- Length : 35mm to 55mm

**- Rod & Pre-Bend Rod**
- 13 different sizes from 50mm to 500mm

**- Clip & Hook**

**- Multi-Axial Adjustable Cross Link**
- 4 different sizes from 30mm to 70mm
- S, M, L, XL

**Multi-Axial System**

- Provides 70° in angle
- Well known technique
- Easy to use

**Wide Application Area**

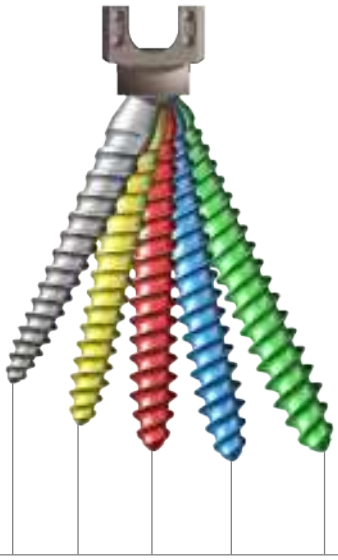
- Suitable for thoraco-lumbar and sacral spine
- Perfect implantation in stenosis, spondylolisthesis, scoliosis, kyphosis, trauma, fractures, tumor and lordosis cases
- Compatible implants and instruments for human anatomy
- Spondylolisthesis (up to Grade 2) without any extra implant or instrument

**Better Design**

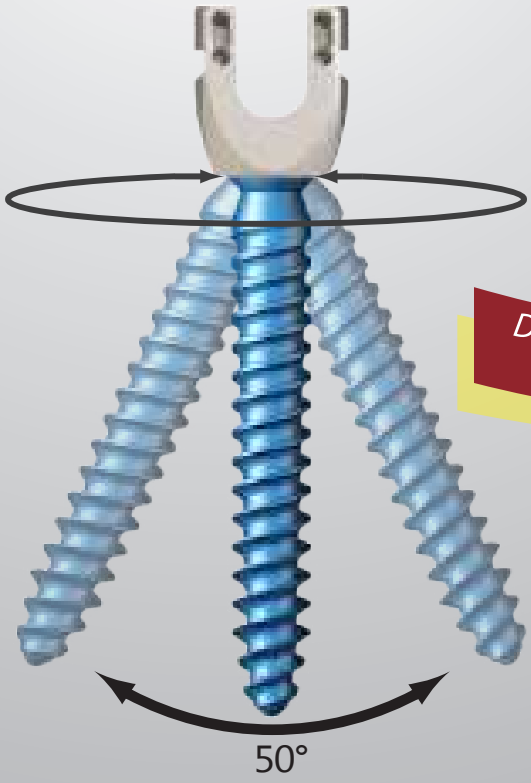
- Double-threaded structure, cortical screw body
- Improved screw tip
- Threaded screw head
- Titanium (6) - Aluminium (4) - Vanadium alloy (ISO 5832-3)
- Biomechanically tested implants according to ASTM F1717 and ASTM F1798

**Implant Features**

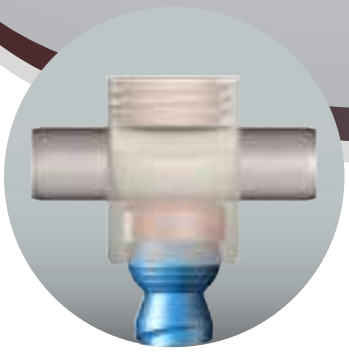
- Color coded screw bodies
- Clip locking mechanism
- Improved adjustable cross link
- 6mm rod system
- Various sizes and types of screw



# PS®
## spine system




Double Threaded



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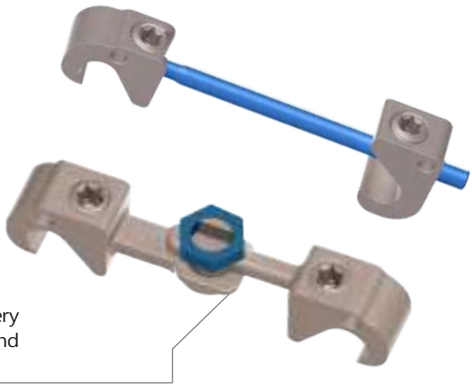
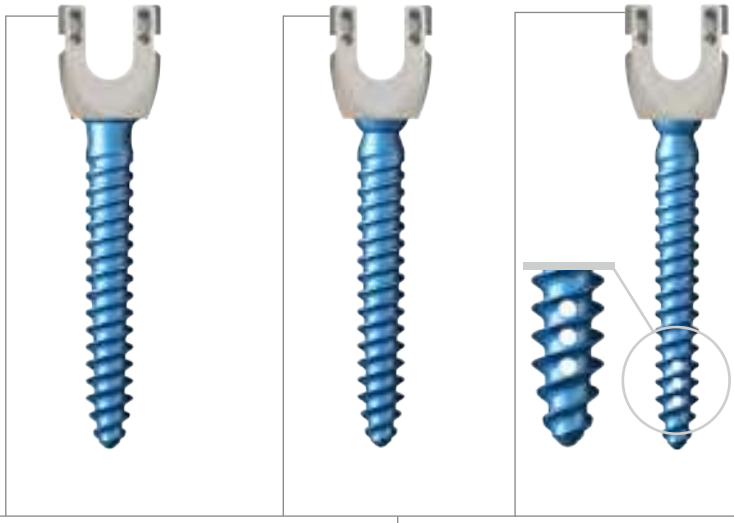
**6mm rod system**
6mm rod system for stronger constructs and universal use

**Screw tip**
Improved screw tip for easy insertion

**Variation of 50°**
Provides a variation of 50° in angle to achieve best anatomic position



**Adjustable transverse connectors**
Adjustable transverse connectors for every construct in 4 sizes between 30mm and 70mm



**- Mono-Axial Screw**
- Diameter : 4.0mm to 8.0mm
- Length : 25mm to 60mm

**- Multi-Axial Screw**
- Diameter : 4.0mm to 8.0mm
- Length : 25mm to 60mm

**- Multi-Axial Cement Type Screw**
- Diameter : 5.5mm and 6.5mm
- Length : 35mm to 55mm

**- Multi-Axial Adjustable Transverse Connector**
- 4 different sizes from 30mm to 70mm
- S, M, L, XL

**- Set Screw & Hook**

**- Rod**
- 13 different sizes from 50mm to 500mm

**Multi-Axial System**

- Provides 50° in angle
- Well known technique
- Easy to use

**Wide Application Area**

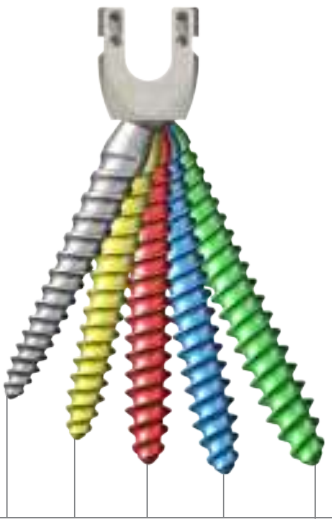
- Suitable for thoraco-lumbar and sacral spine
- Perfect implantation in stenosis, spondylolisthesis, scoliosis, kyphosis, trauma, fractures, tumor and lordosis cases
- Compatible implants and instruments for human anatomy

**Better Design**

- Double-threaded structure, cortical screw body
- Improved screw tip
- Threaded screw head
- Titanium (6) - Aluminium (4) - Vanadium alloy (ISO 5832-3)
- Biomechanically tested implants according to ASTM F1717 and ASTM F1798

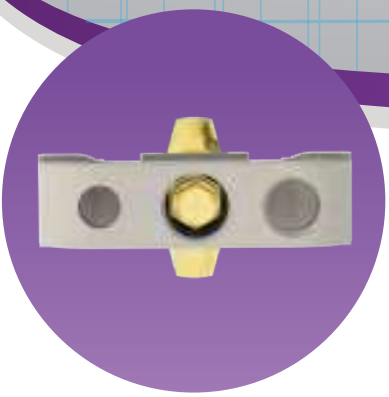
**Implant Features**

- Color coded screw bodies
- Enhanced locking mechanism
- Adjustable transverse connector
- 6mm rod system
- Various sizes and types of screw



# LorX®

## cervical peek cage with blade

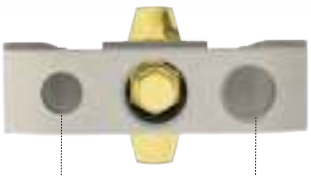


Tria Spine®

*...evolution of spine*

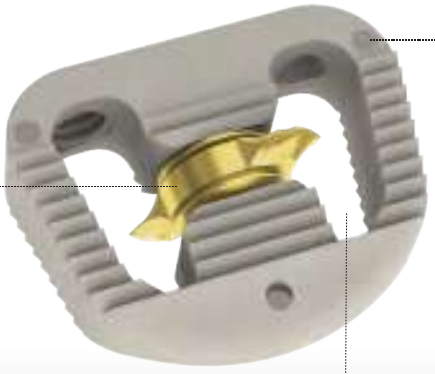
# design features

### Better stability
Two instrument holes for extra stability during insertion
1.5mm fixation of blade into the each endplate



### Anatomical shape
Original and anatomical design for a secure and better placement

### Biocompatibility
Radiolucent and biocompatible PEEK material (VESTAKEEP by Evonik , ASTM F2026) which provides modulus of elasticity similar to the bone



### Tantalum pins
3 tantalum markers (ASTM F560) for the verification of anterior and posterior implant placement

### Special blade design
Specially designed (patent pending) titanium (ASTM F136) blade, positioned in the middle of the cage for perfect fixation
No need of extra fixation implants (plates etc.)

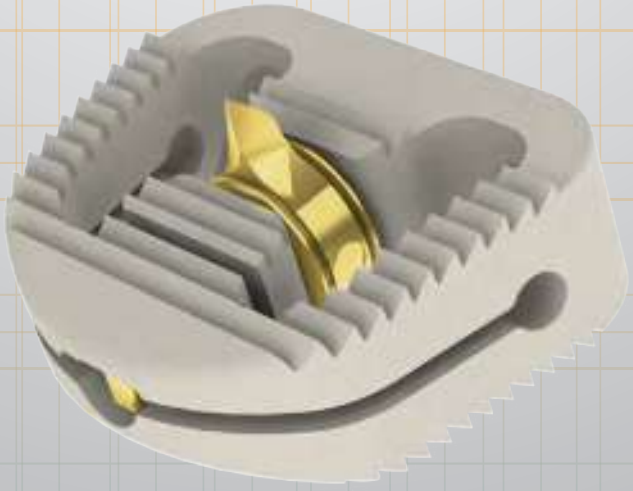
### Enhanced bone fusion
Two adequate graft spaces for bone fusion

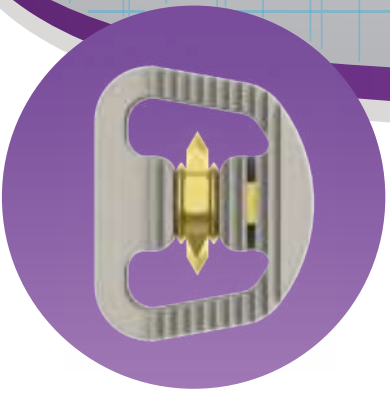
| Cervical PEEK Cage | | | Cervical PEEK Cage with Blade | | |
|---|---|---|---|---|---|
| **Ref** LX-01-525 : | 12X15 mm | 5 mm | **Ref** LX-02-525 : | 12X15 mm | 5 mm |
| **Ref** LX-01-526 : | 12X15 mm | 6 mm | **Ref** LX-02-526 : | 12X15 mm | 6 mm |
| **Ref** LX-01-527 : | 12X15 mm | 7 mm | **Ref** LX-02-527 : | 12X15 mm | 7 mm |
| **Ref** LX-01-528 : | 12X15 mm | 8 mm | **Ref** LX-02-528 : | 12X15 mm | 8 mm |

# LorX®

NEW

## expandable cervical peek cage with blade





Tria Spine®

...evolution of spine

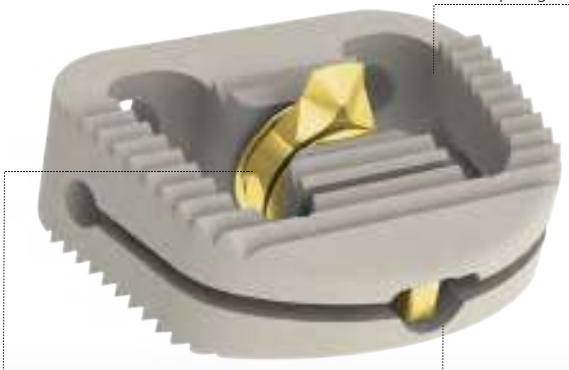
# design features

### Better stability
Enhanced instrumentation for secure insertion

### Anatomical shape
Original and anatomical design for a secure and better placement

### Biocompatibility
Radiolucent and biocompatible PEEK material (VESTAKEEP by Evonik , ASTM F2026) which provides modulus of elasticity similar to the bone

### Enhanced bone fusion
Two adequate graft spaces for bone fusion



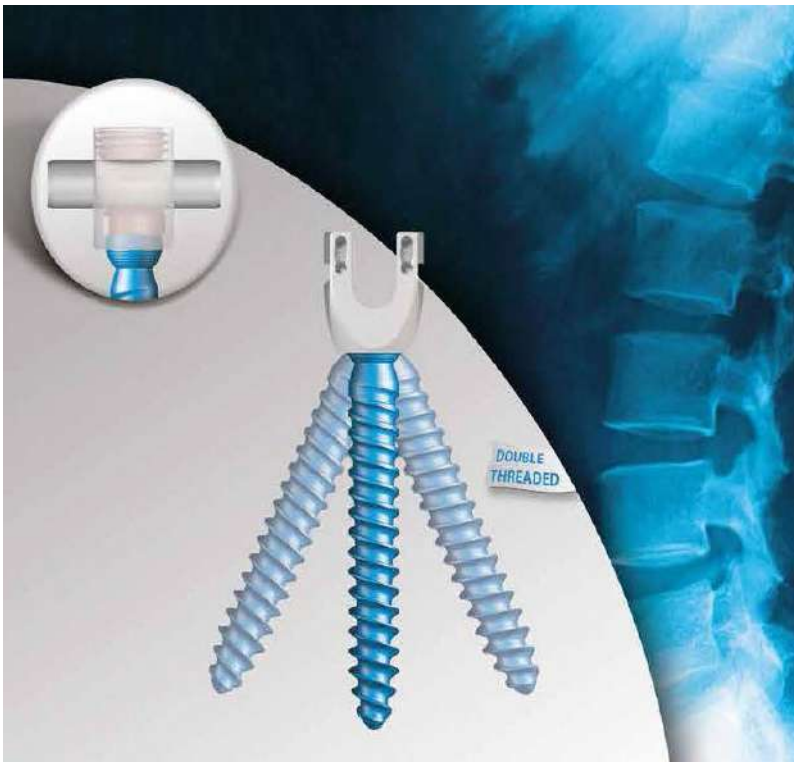
### Special blade design
Specially designed (patent pending) titanium (ASTM F136) blade, positioned in the middle of the cage for perfect fixation
No need of extra fixation implants (plates etc.)

### Improved mechanism
Improved mechanism for secure expanding and placement

| Expandable Cervical PEEK Cage with Blade | | |
|---|---|---|
| **Ref** LX-03-525 : | 12X15 mm | 5 mm |
| **Ref** LX-03-526 : | 12X15 mm | 6 mm |
| **Ref** LX-03-527 : | 12X15 mm | 7 mm |
| **Ref** LX-03-528 : | 12X15 mm | 8 mm |

# PS® SPINE SYSTEM

# TECHNICAL GUIDE




Tria Spine®

SPINE | ORTHOPEDICS

www.triaspine.com

# Description:

PS® Spine System is composed of various types and sizes of pedicle screws, rods, transverse connectors, nuts, clips, hooks, dominos and lateral connectors for thoraco-lumbar and sacral spine.

PS® Spine System is suitable for adults who have enough spinal stability and meet the main indications.

# Material:

System elements are made of titanium alloy (Ti6Al4V) as per ISO 5832-3 (ASTM F136 and BS 7252-3). All system elements are MRI compatible.

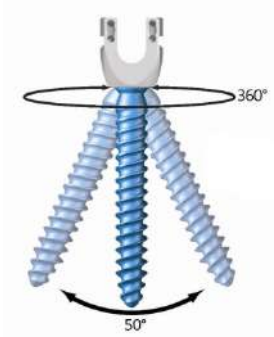
# Indications:

PS® Spine System is indicated for degenerated disc disease, spinal stenosis, scoliosis, kyphosis, trauma, fracture, tumor, lordosis, failed previous fusion (pseudoarthrosis) and spondylo listhesis (grade 1 and 2).

# Contraindications:

Contraindications include but are not limited to:

- Pathological obesity, pregnancy, significant osteoporosis, open wounds, severe local inflammation, dependency on pharmaceutical drugs, drug abuse or alcoholism, mental illnesses, significant osteopenia, known or suspected allergy or intolerance to implant material (foreign body sensitivity to the implant material), acute or chronic infections, lack of patient cooperation.



# Product Features:

**Multi-Axial System**

- Provides 50° in angle
- Well known technique
- Easy to use

**Wide Application Area**

- Suitable for thoraco-lumbar and sacral spine
- Perfect implantation in stenosis, spondylolisthesis, scoliosis, kyphosis, trauma, fractures, tumor and lordosis cases
- Compatible implants and instruments for human anatomy

**Better Design**

- Double-threaded structure, cortical screw body
- Improved screw tip
- Threaded screw head
- Titanium (6) - Aluminium (4) - Vanadium alloy (ISO 5832-3)
- Biomechanically tested implants according to ASTM F1717 and ASTM F1798

**Implant Features**

- Color coded screw bodies
- Enhanced locking mechanism
- Adjustable transverse connector
- 6mm rod system
- Various sizes and types of screw

# Implants:

**Pedicle Screws**

Diameter : 5.5mm, 6.5mm and 7.5mm

Length : 30mm to 55mm

**Multi-Axial Screws**

Diameter : 4.0mm, 4.5mm, 5.5mm, 6.5mm and 7.5mm

Length : 25mm to 60mm

**Multi-Axial Revision Screws**

Diameter : 8.0mm

Length : 30mm to 55mm

**Mono-Axial Reduction Screws**

Diameter : 5.5mm, 6.5mm and 7.5mm

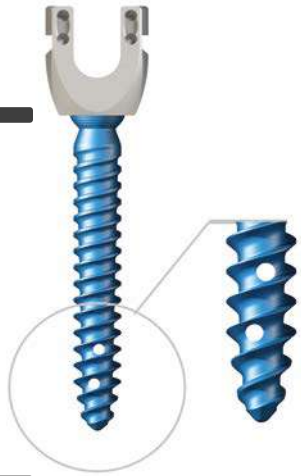
Length : 30mm to 55mm

# Implants:

**Multi-Axial Reduction Screws**

Diameter : 5.5mm, 6.5mm and 7.5mm

Length : 30mm to 55mm



**Multi-Axial Cement Type Screws**

Diameter : 5.5mm and 6.5mm

Length : 35mm to 50mm

**Multi-Axial Iliac Screws**

Diameter : 7.5mm and 8.0mm

Length : 60mm to 110mm

**Rods**

Diameter : 6.0mm

Length : 50mm to 500mm

# Implants:

**Multi-Axial Transverse Links**

Size : Small , Medium, Large and X-Large

**Nut**

PS Set Screw

**Domino Connectors**

Size : Single and Double

**Lateral Connector**

PS Lateral Connector

# Packaging & Sterilization:

System elements are supplied clean but not sterile. Re-usable instruments should be cleaned before use and all system elements should be sterilized following the below mentioned methods.

As per ISO 17665-1:2006, AAMI TIR 12:2004 and other respective standards

# Implants:

| Code | Product Name |
|---|---|
| | Pedicle Screw |
| TP-5530 | PS® Pedicle Screw Set 5.5x30mm |
| TP-5535 | PS® Pedicle Screw Set 5.5x35mm |
| TP-5540 | PS® Pedicle Screw Set 5.5x40mm |
| TP-5545 | PS® Pedicle Screw Set 5.5x45mm |
| TP-5550 | PS® Pedicle Screw Set 5.5x50mm |
| TP-5555 | PS® Pedicle Screw Set 5.5x55mm |
| TP-5560 | PS® Pedicle Screw Set 5.5x60mm |
| TP-6525 | PS® Pedicle Screw Set 6.5x25mm |
| TP-6530 | PS® Pedicle Screw Set 6.5x30mm |
| TP-6535 | PS® Pedicle Screw Set 6.5x35mm |
| TP-6540 | PS® Pedicle Screw Set 6.5x40mm |
| TP-6545 | PS® Pedicle Screw Set 6.5x45mm |
| TP-6550 | PS® Pedicle Screw Set 6.5x50mm |
| TP-6555 | PS® Pedicle Screw Set 6.5x55mm |
| TP-6560 | PS® Pedicle Screw Set 6.5x60mm |
| TP-7525 | PS® Pedicle Screw Set 7.5x25mm |
| TP-7530 | PS® Pedicle Screw Set 7.5x30mm |
| TP-7535 | PS® Pedicle Screw Set 7.5x35mm |
| TP-7540 | PS® Pedicle Screw Set 7.5x40mm |
| TP-7545 | PS® Pedicle Screw Set 7.5x45mm |
| TP-7550 | PS® Pedicle Screw Set 7.5x50mm |
| TP-7555 | PS® Pedicle Screw Set 7.5x55mm |
| | Multi-Axial Screw |
| TM-4025 | PS® Multi-Axial Screw Set 4.0x25mm |
| TM-4030 | PS® Multi-Axial Screw Set 4.0x30mm |
| TM-4035 | PS® Multi-Axial Screw Set 4.0x35mm |
| TM-4040 | PS® Multi-Axial Screw Set 4.0x40mm |
| TM-4045 | PS® Multi-Axial Screw Set 4.0x45mm |
| TM-4525 | PS® Multi-Axial Screw Set 4.5x25mm |
| TM-4530 | PS® Multi-Axial Screw Set 4.5x30mm |
| TM-4535 | PS® Multi-Axial Screw Set 4.5x35mm |
| TM-4540 | PS® Multi-Axial Screw Set 4.5x40mm |
| TM-4545 | PS® Multi-Axial Screw Set 4.5x45mm |
| TM-5525 | PS® Multi-Axial Screw Set 5.5x25mm |
| TM-5530 | PS® Multi-Axial Screw Set 5.5x30mm |
| TM-5535 | PS® Multi-Axial Screw Set 5.5x35mm |
| TM-5540 | PS® Multi-Axial Screw Set 5.5x40mm |
| TM-5545 | PS® Multi-Axial Screw Set 5.5x45mm |
| TM-5550 | PS® Multi-Axial Screw Set 5.5x50mm |
| TM-5555 | PS® Multi-Axial Screw Set 5.5x55mm |
| TM-5560 | PS® Multi-Axial Screw Set 5.5x60mm |
| TM-6525 | PS® Multi-Axial Screw Set 6.5x25mm |
| TM-6530 | PS® Multi-Axial Screw Set 6.5x30mm |
| TM-6535 | PS® Multi-Axial Screw Set 6.5x35mm |
| TM-6540 | PS® Multi-Axial Screw Set 6.5x40mm |
| TM-6545 | PS® Multi-Axial Screw Set 6.5x45mm |
| TM-6550 | PS® Multi-Axial Screw Set 6.5x50mm |
| TM-6555 | PS® Multi-Axial Screw Set 6.5x55mm |
| TM-6560 | PS® Multi-Axial Screw Set 6.5x60mm |
| TM-7525 | PS® Multi-Axial Screw Set 7.5x25mm |
| TM-7530 | PS® Multi-Axial Screw Set 7.5x30mm |
| TM-7535 | PS® Multi-Axial Screw Set 7.5x35mm |
| TM-7540 | PS® Multi-Axial Screw Set 7.5x40mm |
| TM-7545 | PS® Multi-Axial Screw Set 7.5x45mm |
| TM-7550 | PS® Multi-Axial Screw Set 7.5x50mm |
| TM-7555 | PS® Multi-Axial Screw Set 7.5x55mm |
| TM-7560 | PS® Multi-Axial Screw Set 7.5x60mm |

# Implants:

| Code | Product Name |
|---|---|
| | Multi-Axial Revision Screw |
| TM-8030 | PS® Multi-Axial Screw Set 8.0x30mm |
| TM-8035 | PS® Multi-Axial Screw Set 8.0x35mm |
| TM-8040 | PS® Multi-Axial Screw Set 8.0x40mm |
| TM-8045 | PS® Multi-Axial Screw Set 8.0x45mm |
| TM-8050 | PS® Multi-Axial Screw Set 8.0x50mm |
| TM-8055 | PS® Multi-Axial Screw Set 8.0x55mm |
| | Multi-Axial Cement Type Screw |
| TC-5535 | PS® Multi-Axial Screw Cement Type Set 5.5X35mm |
| TC-5540 | PS® Multi-Axial Screw Cement Type Set 5.5X40mm |
| TC-5545 | PS® Multi-Axial Screw Cement Type Set 5.5X45mm |
| TC-5550 | PS® Multi-Axial Screw Cement Type Set 5.5X50mm |
| TC-6535 | PS® Multi-Axial Screw Cement Type Set 6.5X35mm |
| TC-6540 | PS® Multi-Axial Screw Cement Type Set 6.5X40mm |
| TC-6545 | PS® Multi-Axial Screw Cement Type Set 6.5X45mm |
| TC-6550 | PS® Multi-Axial Screw Cement Type Set 6.5X50mm |
| TC-6555 | PS® Multi-Axial Screw Cement Type Set 6.5X55mm |
| | Mono-Axial Reduction Screw |
| TLM-5530 | PS® Reduction Screw Mono Set 5.5x30mm |
| TLM-5535 | PS® Reduction Screw Mono Set 5.5x35mm |
| TLM-5540 | PS® Reduction Screw Mono Set 5.5x40mm |
| TLM-5545 | PS® Reduction Screw Mono Set 5.5x45mm |
| TLM-5550 | PS® Reduction Screw Mono Set 5.5x50mm |
| TLM-6530 | PS® Reduction Screw Mono Set 6.5x30mm |
| TLM-6535 | PS® Reduction Screw Mono Set 6.5x35mm |
| TLM-6540 | PS® Reduction Screw Mono Set 6.5x40mm |
| TLM-6545 | PS® Reduction Screw Mono Set 6.5x45mm |
| TLM-6550 | PS® Reduction Screw Mono Set 6.5x50mm |
| TLM-7530 | PS® Reduction Screw Mono Set 7.5x30mm |
| TLM-7535 | PS® Reduction Screw Mono Set 7.5x35mm |
| TLM-7540 | PS® Reduction Screw Mono Set 7.5x40mm |
| TLM-7545 | PS® Reduction Screw Mono Set 7.5x45mm |
| TLM-7550 | PS® Reduction Screw Mono Set 7.5x50mm |
| | Multi-Axial Reduction Screw |
| TL-5530 | PS® Reduction Screw Multi Set 5.5x30mm |
| TL-5535 | PS® Reduction Screw Multi Set 5.5x35mm |
| TL-5540 | PS® Reduction Screw Multi Set 5.5x40mm |
| TL-5545 | PS® Reduction Screw Multi Set 5.5x45mm |
| TL-5550 | PS® Reduction Screw Multi Set 5.5x50mm |
| TL-6530 | PS® Reduction Screw Multi Set 6.5x30mm |
| TL-6535 | PS® Reduction Screw Multi Set 6.5x35mm |
| TL-6540 | PS® Reduction Screw Multi Set 6.5x40mm |
| TL-6545 | PS® Reduction Screw Multi Set 6.5x45mm |
| TL-6550 | PS® Reduction Screw Multi Set 6.5x50mm |
| TL-7530 | PS® Reduction Screw Multi Set 7.5x30mm |
| TL-7535 | PS® Reduction Screw Multi Set 7.5x35mm |
| TL-7540 | PS® Reduction Screw Multi Set 7.5x40mm |
| TL-7545 | PS® Reduction Screw Multi Set 7.5x45mm |
| TL-7550 | PS® Reduction Screw Multi Set 7.5x50mm |

# Implants:

| Code | Product Name |
|---|---|
| | Multi-Axial Iliac Screw |
| TI-7560 | PS® Multi-Axial Iliac Screw Set 7.5x60mm |
| TI-7570 | PS® Multi-Axial Iliac Screw Set 7.5x70mm |
| TI-7580 | PS® Multi-Axial Iliac Screw Set 7.5x80mm |
| TI-7590 | PS® Multi-Axial Iliac Screw Set 7.5x90mm |
| TI-7500 | PS® Multi-Axial Iliac Screw Set 7.5x100mm |
| TI-7510 | PS® Multi-Axial Iliac Screw Set 7.5x110mm |
| TI-8060 | PS® Multi-Axial Iliac Screw Set 8.0x60mm |
| TI-8070 | PS® Multi-Axial Iliac Screw Set 8.0x70mm |
| TI-8080 | PS® Multi-Axial Iliac Screw Set 8.0x80mm |
| TI-8090 | PS® Multi-Axial Iliac Screw Set 8.0x90mm |
| TI-8000 | PS® Multi-Axial Iliac Screw Set 8.0x100mm |
| TI-8010 | PS® Multi-Axial Iliac Screw Set 8.0x110mm |
| TI-9060 | PS® Multi-Axial Iliac Screw Set 9.0x60mm |
| TI-9070 | PS® Multi-Axial Iliac Screw Set 9.0x70mm |
| TI-9080 | PS® Multi-Axial Iliac Screw Set 9.0x80mm |
| TI-9090 | PS® Multi-Axial Iliac Screw Set 9.0x90mm |
| TI-9000 | PS® Multi-Axial Iliac Screw Set 9.0x100mm |
| TI-9010 | PS® Multi-Axial Iliac Screw Set 9.0x110mm |
| | Rod |
| TR-0050 | PS® Rod 6.0 x 50mm |
| TR-0060 | PS® Rod 6.0 x 60mm |
| TR-0070 | PS® Rod 6.0 x 70mm |
| TR-0080 | PS® Rod 6.0 x 80mm |
| TR-0090 | PS® Rod 6.0 x 90mm |
| TR-0100 | PS® Rod 6.0 x 100mm |
| TR-0120 | PS® Rod 6.0 x 120mm |
| TR-0140 | PS® Rod 6.0 x 140mm |
| TR-0160 | PS® Rod 6.0 x 160mm |
| TR-0200 | PS® Rod 6.0 x 200mm |
| TR-0400 | PS® Rod 6.0 x 400mm |
| TR-0500 | PS® Rod 6.0 x 500mm |
| | Multi-Axial Transverse Link |
| TT-0030 | PS® Multi-Axial Transverse Link S |
| TT-0034 | PS® Multi-Axial Transverse Link M |
| TT-0040 | PS® Multi-Axial Transverse Link L |
| TT-0050 | PS® Multi-Axial Transverse Link XL |
| | Set Screw |
| TS-0010 | PS® Set Screw |
| | Domino |
| TDS-2205 | PS® Domino Single |
| TDD-2210 | PS® Domino Double |
| | Lateral Connector |
| TLC-1100 | PS® Multi-Axial Offset Lateral Connector |
| TLC-1110 | PS® Lateral Connector |

# Additional Information:

**WARNING:**

**BY LAW, THIS DEVİCE CAN BE SOLD BY OR ON THE ORDER OF A PHYSICIAN.**

System elements can only be implanted by a surgeon with a good working knowledge of the device, its applications, the instruments and the required surgical technique.

**WARNING:**

**Please contact Tria Spine or authorized representative for further information about this product.**


## Tria Spine Medikal Ltd. Sti

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Fax: +90 312 2194103
E-mail: mail@triaspine.com

**www.triaspine.com**


Tria Spine®
SPINE | ORTHOPEDICS

# PS® MINI OCCIPITO-CERVICO-THORACIC SYSTEM

# TECHNICAL GUIDE

Tria Spine®

SPINE | ORTHOPEDICS

www.triaspine.com

# Description:

PS® Mini Occipito-Cervico-Thoracic System is a posterior spinal fixation system for stabilization of the upper spine (occiput-T3) in the aim of the treatment of occipito-cervico-thoracic spine diseases.

**WARNING: System is not intended for thoracic (T4-T12) and lumbar spine.** System can also be linked to thoraco-lumbar systems via hybrid rods, domino connector and inline rod connector.

PS® Mini Occipito-Cervico-Thoracic System is suitable for adults who have enough spinal stability and meet the main indications.

# Material:

System elements are made of titanium alloy (Ti6Al4V) as per ISO 5832-3 (ASTM F136 and BS 7252-3). All system elements are MRI compatible.

# Indications:

PS® Mini Occipito-Cervico-Thoracic System is indicated for degenerated disc disease, spinal stenosis, occipitocervical dislocation, atlantoaxial fracture with instability, trauma, fracture/dislocation, tumors, failed previous fusion (pseudoarthrosis) and spondylolisthesis.

# Contraindications:

Contraindications include but are not limited to:

- Pathological obesity, pregnancy, significant osteoporosis, open wounds, severe local inflammation, dependency on pharmaceutical drugs, drug abuse or alcoholism, mental illnesses, significant osteopenia, known or suspected allergy or intolerance to implant material (foreign body sensitivity to the implant material), acute or chronic infections, lack of patient cooperation.

# Product Features:

**Multi-Axial System**

- Provides 65° in angle
- Well known technique
- Easy to use

**Wide Application Area**

- Suitable for upper spine (occiput-T3)
- Perfect implantation in stenosis, spondylolisthesis, trauma, fractures, tumor and occipito cervical dislocation cases
- Compatible implants and instruments for human anatomy

**Better Design**

- Special screw body
- Improved screw tip
- Titanium alloy (Ti6Al4V - ISO 5832-3)
- Biomechanically tested implants according to ASTM standards

**Implant Features**

- Color coded screw bodies
- Enhanced locking mechanism
- Adjustable transverse connector
- 3.5mm rod system
- Various sizes and types of implants

# Implants:

**Multi-Axial Screws**

Diameter : 3.5mm and and 4.0mm

Length : 10mm to 42mm

**Nut**

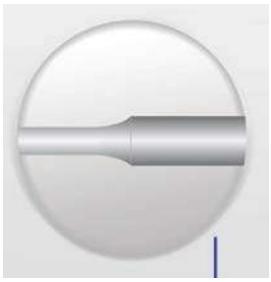
PS MINI Nut

**Rods**

Diameter : 3.5mm

Length : 80mm to 240mm

Hybrid Rod : Diameter from 3.5mm to 6.0mm in 480mm length



**Adjustable Transverse Connector**

Size : Small , Medium and Large

# Implants:

**Occipital Plate**

Size : Small , Medium, and Multi-Level

**Connectors**

PS MINI Lateral Connector

PS MINI Domino Connector 3.5mm to 6.0mm

PS MINI Inline Rod Connector 3.5mm to 6.0mm

**Bone Screw**

Diameter : 4.0mm

Length : 6mm to 14mm

# Packaging & Sterilization:

System elements are supplied clean but not sterile. Re-usable instruments should be cleaned before use and all system elements should be sterilized following the below mentioned methods.

As per ISO 17665-1:2006, AAMI TIR 12:2004 and other respective standards

# Implants:

| Code | Product Name |
|---|---|
| Multi-Axial Screw | |
| OCM-3510 | PS® Mini Cervical Multi-Axial Screw+Nut 3.5x10mm |
| OCM-3512 | PS® Mini Cervical Multi-Axial Screw+Nut 3.5x12mm |
| OCM-3514 | PS® Mini Cervical Multi-Axial Screw+Nut 3.5x14mm |
| OCM-3516 | PS® Mini Cervical Multi-Axial Screw+Nut 3.5x16mm |
| OCM-3518 | PS® Mini Cervical Multi-Axial Screw+Nut 3.5x18mm |
| OCM-3520 | PS® Mini Cervical Multi-Axial Screw+Nut 3.5x20mm |
| OCM-3522 | PS® Mini Cervical Multi-Axial Screw+Nut 3.5x22mm |
| OCM-3524 | PS® Mini Cervical Multi-Axial Screw+Nut 3.5x24mm |
| OCM-3526 | PS® Mini Cervical Multi-Axial Screw+Nut 3.5x26mm |
| OCM-3528 | PS® Mini Cervical Multi-Axial Screw+Nut 3.5x28mm |
| OCM-3530 | PS® Mini Cervical Multi-Axial Screw+Nut 3.5x30mm |
| OCM-3532 | PS® Mini Cervical Multi-Axial Screw+Nut 3.5x32mm |
| OCM-3536 | PS® Mini Cervical Multi-Axial Screw+Nut 3.5x36mm |
| OCM-3540 | PS® Mini Cervical Multi-Axial Screw+Nut 3.5x40mm |
| | |
| OCM-4010 | PS® Mini Cervical Multi-Axial Screw+Nut 4.0x10mm |
| OCM-4012 | PS® Mini Cervical Multi-Axial Screw+Nut 4.0x12mm |
| OCM-4014 | PS® Mini Cervical Multi-Axial Screw+Nut 4.0x14mm |
| OCM-4016 | PS® Mini Cervical Multi-Axial Screw+Nut 4.0x16mm |
| OCM-4018 | PS® Mini Cervical Multi-Axial Screw+Nut 4.0x18mm |
| OCM-4020 | PS® Mini Cervical Multi-Axial Screw+Nut 4.0x20mm |
| OCM-4022 | PS® Mini Cervical Multi-Axial Screw+Nut 4.0x22mm |
| OCM-4024 | PS® Mini Cervical Multi-Axial Screw+Nut 4.0x24mm |
| OCM-4026 | PS® Mini Cervical Multi-Axial Screw+Nut 4.0x26mm |
| OCM-4028 | PS® Mini Cervical Multi-Axial Screw+Nut 4.0x28mm |
| OCM-4030 | PS® Mini Cervical Multi-Axial Screw+Nut 4.0x30mm |
| OCM-4032 | PS® Mini Cervical Multi-Axial Screw+Nut 4.0x32mm |
| OCM-4034 | PS® Mini Cervical Multi-Axial Screw+Nut 4.0x34mm |
| OCM-4036 | PS® Mini Cervical Multi-Axial Screw+Nut 4.0x36mm |
| OCM-4038 | PS® Mini Cervical Multi-Axial Screw+Nut 4.0x38mm |
| OCM-4040 | PS® Mini Cervical Multi-Axial Screw+Nut 4.0x40mm |
| OCM-4042 | PS® Mini Cervical Multi-Axial Screw+Nut 4.0x42mm |

# Implants:

| Code | Product Name |
|---|---|
| Nut | |
| OCN-0010 | PS® Mini Nut |
| Rod | |
| OCR-3580 | PS® Mini Titanium Rod 3.5x80mm |
| OCR-3160 | PS® Mini Titanium Rod 3.5x160mm |
| OCR-3240 | PS® Mini Titanium Rod 3.5x240mm |
| Hybrid Rod | |
| OCR-3480 | PS® Mini Titanium Hybrid Rod 3.5mm-6.0mm x 480mm |
| Adjustable Transverse Connector | |
| OCT-0010 | PS® Mini Adjustable Transverse Connector S |
| OCT-0020 | PS® Mini Adjustable Transverse Connector M |
| OCT-0030 | PS® Mini Adjustable Transverse Connector L |
| Lateral Connector | |
| OCL-0010 | PS® Mini Lateral Connector |
| Domino | |
| OCD-0010 | PS® Mini Domino Connector 3.5mm-6.0mm |
| OCD-0020 | PS® Mini Inline Rod Connector 3.5mm-6.0mm |
| Occipital Plate | |
| OCP-0010 | PS® Mini Occipital Plate Small |
| OCP-0020 | PS® Mini Occipital Plate Medium |
| OCP-0030 | PS® Mini Multi-Level Plate |
| Bone Screw | |
| OCS-4006 | PS® Mini Bone Screw 4.0x6mm |
| OCS-4008 | PS® Mini Bone Screw 4.0x8mm |
| OCS-4010 | PS® Mini Bone Screw 4.0x10mm |
| OCS-4012 | PS® Mini Bone Screw 4.0x12mm |
| OCS-4014 | PS® Mini Bone Screw 4.0x14mm |
| OCS-4016 | PS® Mini Bone Screw 4.0x16mm |
| OCS-4018 | PS® Mini Bone Screw 4.0x18mm |
| OCS-4020 | PS® Mini Bone Screw 4.0x20mm |
| OCS-4022 | PS® Mini Bone Screw 4.0x22mm |
| OCS-4024 | PS® Mini Bone Screw 4.0x24mm |

HumanTech
Medical Devices

# ADONIS®

## Transforaminale lumbale interkorporelle Fusion

TLIF

Die TLIF-Technik arbeitet mit einem unilateralen Zugang zum Bandscheibenfach durch das Foramen intervertebralis. Dadurch sorgt das TLIF-Verfahren für einen einseitigen posterioren Zugang zu einer „360°“-Fusion, was unter anderem folgende Vorteile gegenüber der PLIF-Technik bietet:

- unilaterale Facettenresektion
- Erhalt des Wirbelbogens
- Erhalt der kontralateralen Facette
- Minimale Retraktion der Dura
- Geringeres Risiko einer intraduralen Vernarbung
- Revisionsstrategie - nur einseitige Vernarbung

ADONIS®-TLIF ist ein intelligentes - durch sein Instrumentarium - hochrationelles Interbody-Device-System und stellt somit eine allseits anerkannte Produktlinie mit folgenden Vorzügen dar:

## anatomisch

- Geometrie analog der Anatomie im Querschnitt und im Sagittalprofil
- Großzügige Auflagefläche - reduzierte Migrationsgefahr

## stabil

- Antegrade Zahnung zur stabilen Verankerung
- Konvexe Auflageflächen zur sicheren und dauerhaften Sitzgenauigkeit
- Signifikant erhöhte Ausziehkräfte
- Extrem hoher Reibungskoeffizient

## integer

- Große Öffnung zum Befüllen für eine schnelle Fusion
- Die zur Implantatmitte konisch verlaufende Innengeometrie des Cages hält das Füllmaterial im Cage und erhöht das Füllvolumen

## modular

Durch freie Wählbarkeit aus 3 Werkstoffen:

**• Titan**

Als besonders bioverträglich und entsprechend modifizierbar hat sich das Metall Titan herausgestellt. Es ist erwiesen, dass die unterschiedlichen Reaktionen von menschlichen Zellen durch das nur wenige Nanometer dünne Oberflächenoxid der Titanwerkstoffe verursacht werden.

**• PEEK**

Das Material weist eine hohe Biokompatibilität auf und charakterisiert sich durch eine knochenähnliche Elastizität. Weiterer Vorteil ist die Artefaktfreiheit des Materials

**• PEEK-Titanbeschichtet**

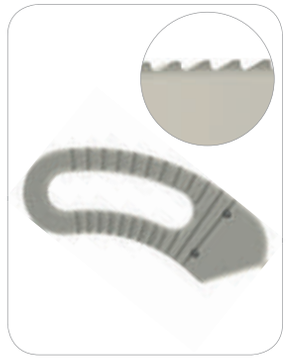
Die Titanbeschichtung, die durch ihr ausgewogenes Verhältnis zwischen Porentiefe, Porosität und Rauhigkeit eine optimale Grundlage bietet, erweist sich als ideal für das Andocken von Knochenzellen an das Implantat. Die osteoinduktiven Eigenschaften des Titans ermöglichen ein direktes Anwachsen des Knochens an das Implantat.

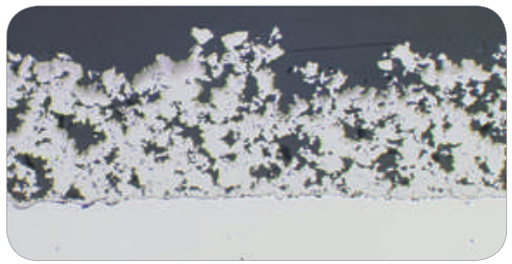

Made in Germany

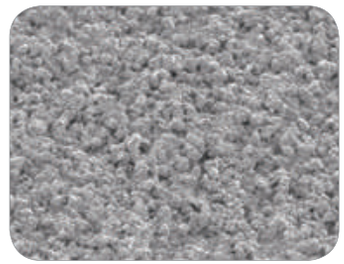
# ADONIS® -TLIF

Interbody Device System

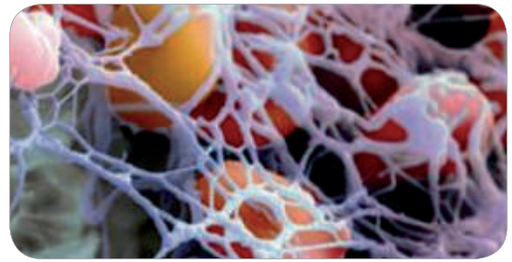
## Produktspezifische Vorteile

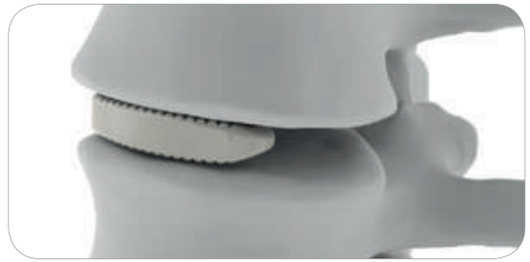






- modular
- integer
- stabil
- anatomisch
- osseointegrativ





## ADONIS®-TLIF Classic

ADONIS® Classic ist ein solides Titan-Interbody-Device-System und stellt somit eine allseits anerkannte Produktlinie für thorakolumbale Indikationen dar. Kombiniert mit einem zuverlässigen und einfachen Instrumentarium wird ADONIS® Classic zu der Lösung für thorakolumbale, interkorporelle Fusionen. Die neuesten Erkenntnisse werden zur Herstellung von Titan-Implantatwerkstoffen mit maßgeschneiderten Oberflächeneigenschaften genutzt. Wir verwenden ausschließlich Titan Ti 6Al-4V ELI (nach DIN ISO 5832-3).

TITAN

## ADONIS®-TLIF Avantgarde

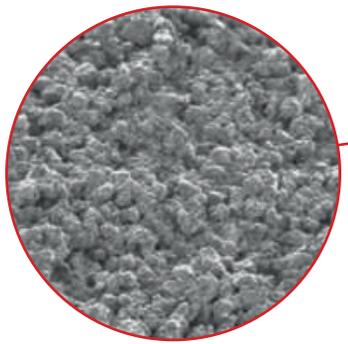
ADONIS® Avantgarde ist ein Implantat aus bioverträglichem PEEK-Optima® zur thorakolumbalen, interkorporellen Fusion und wird bei degenerativen Bandscheibenerkrankungen und Instabilitäten eingesetzt. Das röntgentransparente Material ermöglicht eine schnelle und einfache Beurteilung der Knochenstruktur und des Fusionsprozesses. Röntgenmarker dienen der Positionsverifizierung. Die mechanische Festigkeit von 3,6 GPa ermöglicht eine optimale Kraftübertragung zwischen dem Implantatmaterial und dem natürlichen Knochen. Dadurch werden die Prozesse der Knochenheilung stimuliert. Unser PEEK-Material ist nach ISO 10993 getestet und nach USP-VI klassifiziert, die entsprechenden FDA Device und Drug Master Files sind erhältlich. PEEK ist hinsichtlich der Eigenschaften und den Zulassungen für die Verwendung als Implantatwerkstoff prädestiniert.

PEEK

## ADONIS® Exclusive

ADONIS® Exclusive setzt im Bereich der thorakolumbalen, interkorporellen Fusion vollkommen neue Maßstäbe. Durch die Titanbeschichtungen der neuen ADONIS® Exclusive-Cages werden die Vorteile verschiedener Materialen in einem Implantat genutzt. Die Basis des Implantates ist ein solider PEEK-Kern. Dieser Kern wird zur Vergrößerung der Oberfläche, und somit auch zur Maximierung der Kontaktzone zwischen Implantat und Wirbelkörperoberfläche mit Titan beschichtet.

R-PEEK-Ti-coated

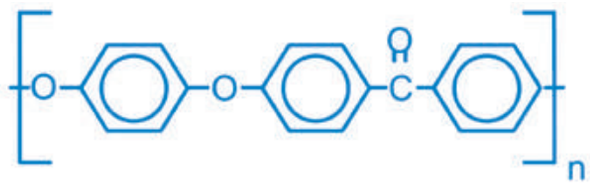


Die Titanbeschichtung, die durch ihr ausgewogenes Verhältnis zwischen Porentiefe, Porosität und Rauhigkeit eine optimale Grundlage bietet, erweist sich als ideal für das Andocken von Knochenzellen in das Implantat. Die osteoinduktiven Eigenschaften des Titans ermöglichen ein direktes Anwachsen des Knochens an das Implantat.

### Eigenschaften PEEK und R-PEEK-Ti-coated

- PEEK ist röntgendurchlässig und erzeugt keine Artefakte
- Positionsverifizierung mittels Röntgenmarker
- Anatomische Form und gezahnte, sowie Ti-beschichtete Oberfläche
- Die halbrunde Form sorgt für eine maximale Kontaktzone
- Möglichkeit einer Befüllung mit Knochen oder Knochenersatzmaterial für eine verbesserte Knochendurchbauung
- Feste Verbindung zum Einsetzinstrument

PEEK-OPTIMA® ist ein polyaromatischer, semikristalliner Thermoplast, der auf der Grundformel (-C6H4-O-C6H4-O-C6H4-CO-)$_n$ basiert und allgemein als Polyetheretherketon bekannt ist.



## **Classic** Titanium

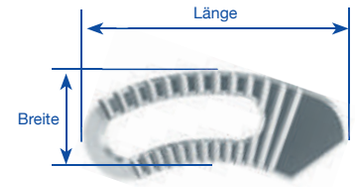
| Art.Nr. | Bezeichnung | Länge | Breite | Höhe | Winkel |
|---|---|---|---|---|---|
| 1801051207 | Adonis TLIF Ti 35x12x07 | 35 | 12 | 07 | |
| 1801051209 | Adonis TLIF Ti 35x12x09 | 35 | 12 | 09 | |
| 1801051211 | Adonis TLIF Ti 35x12x11 | 35 | 12 | 11 | |
| 1801051213 | Adonis TLIF Ti 35x12x13 | 35 | 12 | 13 | |
| 1801051215 | Adonis TLIF Ti 35x12x15 | 35 | 12 | 15 | |
| 1801091207 | Adonis TLIF Ti 35x12x07 5° | 35 | 12 | 07 | 5° |
| 1801091209 | Adonis TLIF Ti 35x12x09 5° | 35 | 12 | 09 | 5° |
| 1801091211 | Adonis TLIF Ti 35x12x11 5° | 35 | 12 | 11 | 5° |
| 1801091213 | Adonis TLIF Ti 35x12x13 5° | 35 | 12 | 13 | 5° |
| 1801091215 | Adonis TLIF Ti 35x12x15 5° | 35 | 12 | 15 | 5° |

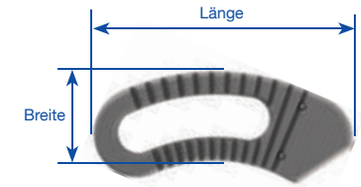
## **Exclusive** R-PEEK-Ti-coated

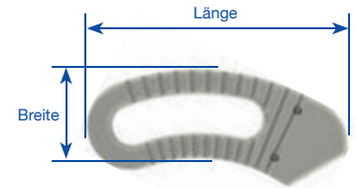
| Art.Nr. | Bezeichnung | Länge | Breite | Höhe | Winkel |
|---|---|---|---|---|---|
| 1803061207 | Adonis-TLIF R-PEEK-Ti 35x12x07 | 35 | 12 | 07 | |
| 1803061209 | Adonis-TLIF R-PEEK-Ti 35x12x09 | 35 | 12 | 09 | |
| 1803061211 | Adonis-TLIF R-PEEK-Ti 35x12x11 | 35 | 12 | 11 | |
| 1803061213 | Adonis-TLIF R-PEEK-Ti 35x12x13 | 35 | 12 | 13 | |
| 1803061215 | Adonis-TLIF R-PEEK-Ti 35x12x15 | 35 | 12 | 15 | |

## **Avantgarde** PEEK

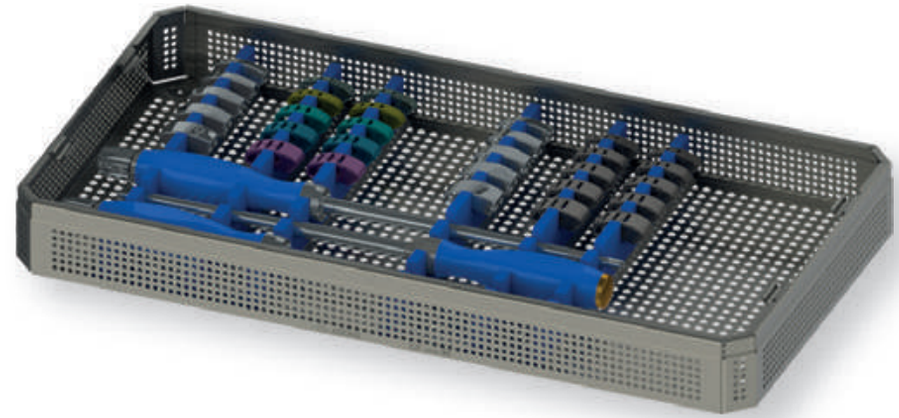
| Art.Nr. | Bezeichnung | Länge | Breite | Höhe | Winkel |
|---|---|---|---|---|---|
| 1801041207 | Adonis TLIF PEEK 35x12x07 | 35 | 12 | 07 | |
| 1801041209 | Adonis TLIF PEEK 35x12x09 | 35 | 12 | 09 | |
| 1801041211 | Adonis TLIF PEEK 35x12x11 | 35 | 12 | 11 | |
| 1801041213 | Adonis TLIF PEEK 35x12x13 | 35 | 12 | 13 | |
| 1801041215 | Adonis TLIF PEEK 35x12x15 | 35 | 12 | 15 | |
| 1801041307 | Adonis TLIF PEEK 35x12x07 5° | 35 | 12 | 07 | 5° |
| 1801041309 | Adonis TLIF PEEK 35x12x09 5° | 35 | 12 | 09 | 5° |
| 1801041311 | Adonis TLIF PEEK 35x12x11 5° | 35 | 12 | 11 | 5° |
| 1801041313 | Adonis TLIF PEEK 35x12x13 5° | 35 | 12 | 13 | 5° |
| 1801041315 | Adonis TLIF PEEK 35x12x15 5° | 35 | 12 | 15 | 5° |



| Art.Nr. | Bezeichnung | |
|---|---|---|
| 1801011207<br>1801011209<br>1801011211<br>1801011213<br>1801011215<br>1801011307<br>1801011309<br>1801011311<br>1801011313<br>1801011315 | TLIF Trial 35x12x07mm<br>TLIF Trial 35x12x09mm<br>TLIF Trial 35x12x11mm<br>TLIF Trial 35x12x13mm<br>TLIF Trial 35x12x15mm<br>TLIF Trial 35x12x07mm 5°<br>TLIF Trial 35x12x09mm 5°<br>TLIF Trial 35x12x11mm 5°<br>TLIF Trial 35x12x13mm 5°<br>TLIF Trial 35x12x15mm 5° |  |
| 1801010403 | TLIF Trial-Inserter |  |
| 1701010600 | Extractor Handle |  |
| 1801010401 | TLIF Inserter |  |
| 1801010000 | Multiaxial TLIF Inserter |  |
| 1801010002 | Slap Hammer |  |



Die Implantatoberfläche hat für die Implantatverankerung und die Implantatverträglichkeit an der Grenzfläche Implantat/angrenzendes Gewebe eine große Bedeutung. Der Erfolg und die Geschwindigkeit der Osseointegration werden maßgeblich durch die Oberfläche des Implantates beeinflusst.

Mithilfe einer idealen Implantatoberfläche können die biologischen Reaktionen zwischen Implantat und Knochen optimiert und damit eine frühzeitigere funktionelle Belastung der Implantate erreicht werden. Der Langzeiterfolg eines Implantattherapie-Konzeptes wird von multiplen Faktoren bestimmt, vor allem aber durch die Knochendichte des Implantatlagers, das Implantatdesign sowie der Implantatoberfläche. Die Zusammensetzung, Rauhigkeit und Topographie der Implantatoberfläche am Interface spielen eine wichtige Rolle für die Primärstabilität und sichere Osseointegration. Rauhe Implantatoberflächen beeinflussen und stimulieren die Zellaktivität umliegender Knochenstrukturen. Die Zellproliferation und -differenzierung, Matrixsynthese und Produktion des “Tissue Growth Factors” werden gefördert und führen zu einem dichten Knochen-Implantat-Verbund.

Spezifische Rauhigkeiten der Implantatoberfläche fördern das Regenerationspotential am Interface und damit die klinische Implantatfixierung. Im Vergleich zu maschinell bearbeiteten Implantatoberflächen zeigt die moderat raue Oberfläche von ADONIS® Exclusive eine dichtere Knochenanlagerung mit signifikant erhöhten Ausziehkräften (Removal Load) und einem extrem hohen Reibungskoeffizienten zur Primärstabilisierung. Daraus ergibt sich eine beschleunigte Osseointegration dieser Implantate mit der Möglichkeit einer früheren Belastung.

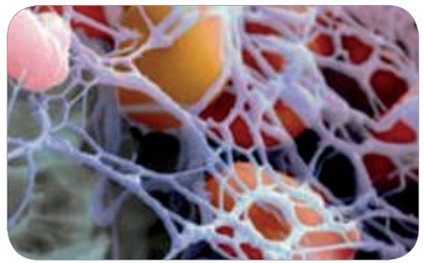


Fig. 1

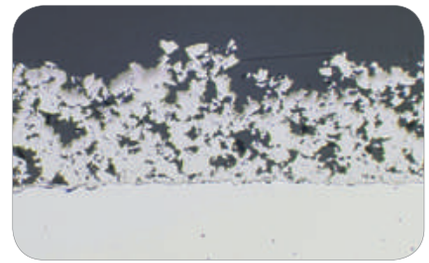


Fig. 2

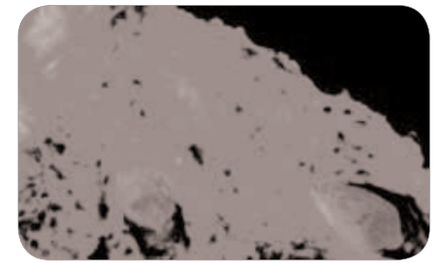


Fig. 3

HumanTech
Medical Devices

# ADONIS®

## Anterior lumbar interbody fusion

ALIF

ADONIS®-ALIF cages are indicated for anterior lumbar vertebral body fusion. The implants are designed to be perfectly adapted to the anatomy of vertebral bodies in order to re-establish lordosis for reliable normalisation of the alignment of the spinal column and to provide stability and optimum conditions for fusion with the following indications:

- herniated discs
- calcified herniated discs
- mechanical instabilities
- calcification of the posterior longitudinal ligament
- osteochondrosis
- spinal canal stenosis

ADONIS®-ALIF is an intelligent and, by virtue of the associated set of instruments, highly rational interbody device system that is a widely recognised and accepted product line offering the following benefits:

## Anatomical

- Geometry is identical to the patient's own sectional and sagittal anatomy
- Generous contact surface - reduced risk of migration

## Stable

- Antegrade toothing for stable anchorage
- Cranial convex contact surfaces for secure and permanent high precision seating
- Significantly increased extraction forces
- Extremely high friction coefficient

## Reliable

- Large filling apertures for rapid fusion
- Internal annular groove holds the filling material in the cage and increases the filling volume

## Modular

Thanks to the choice of 3 materials:

**• Titanium**

The metal titanium has proven to be especially biocompatible and correspondingly easy to modify. It is proven that the various reactions of human cells are initiated by the surface oxides of the titanium materials, which are just a few nanometres thin.

**• PEEK**

The material exhibits a high level of biocompatibility and is characterised by a bone-like elasticity. A further advantage lies in the material's abstract-free properties

**• PEEK titanium-coated**

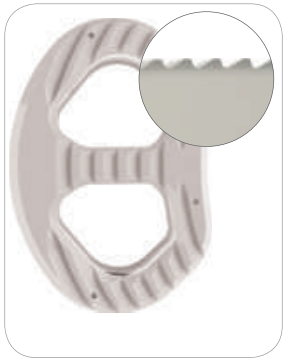
The titanium coating which, due to the relation between pore depth, porosity and roughness, provides an optimum substrate, has proven to be ideal for the docking of bone cells to the implant. The osteoinductive properties of titanium enable bone to take root directly on the implant.

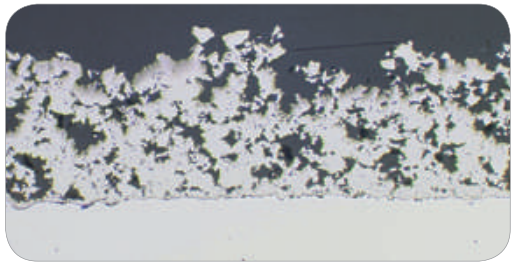

Made in Germany

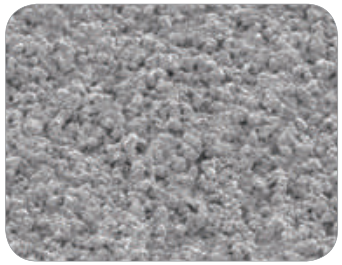
# ADONIS® -ALIF

Interbody Device System

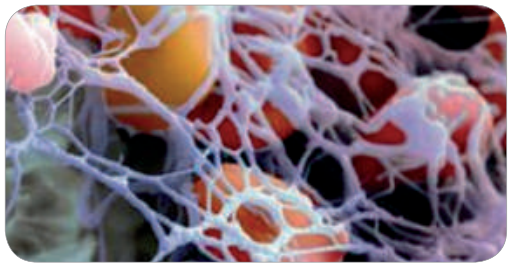
## Product-specific advantages







- Modular
- Reliable
- Stable
- Anatomical



## ADONIS®-ALIF Classic

ADONIS® Classic is a solid titanium interbody device system and is a generally accepted product line for thoracolumbar indications. Coupled with a reliable and simple set of instruments, ADONIS® Classic is an ideal solution for thoracolumbar interbody fusions. The latest findings are used in the manufacturing of titanium implant materials with tailor-made surface properties. We exclusively use titanium
Ti 6Al-4V ELI (as per DIN ISO 5832-3).

TITANIUM



## ADONIS®-ALIF Avantgarde

ADONIS® Avantgarde is an implant made from biocompatible PEEK-Optima® for the thoracolumbar interbody fusion used to treat degenerative disc diseases and instabilities.

This X-ray transparent material enables rapid and straightforward assessment of the bone structure and the fusion process. X-ray markers serve to verify positioning. A mechanical stability of 3.6 GPa allows for optimal load transmission between the implant material and natural bone. This stimulates bone healing processes.

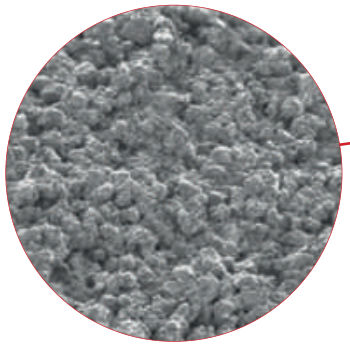
Our PEEK material has been tested in accordance with ISO 10993 and classified in accordance with US P-VI, and the relevant FDA Device and Drug Master Files are available. Thanks to its material properties and its approval certificates, PEEK is predestined for use as an implant material.

PEEK

## ADONIS® Exclusive

ADONIS® Exclusive sets new benchmarks in the area of thoracolumbar interbody fusion. The titanium coatings of the new ADONIS® Exclusive cages combine the advantages of various materials in one implant. The basis of the implant is a solid Peek core. This core is coated with titanium to increase the surface area and thus also to maximise the contact zone between the implant and the vertebral body surface.

R-PEEK-Ti-coated

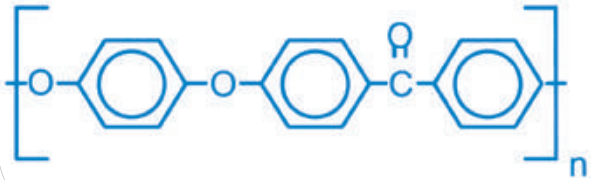


The titanium coating that, due to its balanced relationship between pore depth, porosity and roughness, affords an optimum substrate has proven to be ideal for docking bone cells in the implant. The osteoinductive properties of titanium enable bone to take root directly on the implant.

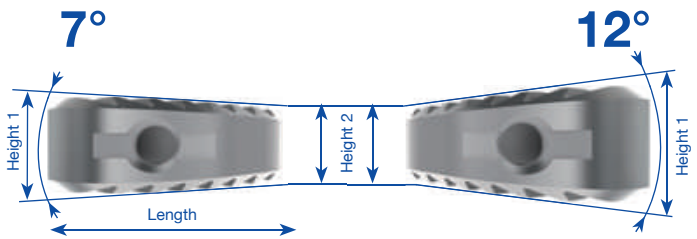
### Properties of PEEK and R-PEEK-Ti-coated

- PEEK is transparent to X-rays and does not produce artefacts
- Position verification using X-ray markers
- Anatomical form and toothed or Ti-coated surface
- The semi-circular shape provides for a maximum contact area
- It can optionally be filled with bone or bone replacement material for improved bone grafting
- Firm connection to the application instrument

PEEK-OPTIMA® is a polyaromatic, semi-crystalline thermoplastic, which is based on the basic formula (-C6H4-O-C6H4-O-C6H4-CO-)n and generally known as a polyether ether ketone.



## Classic
Titanium

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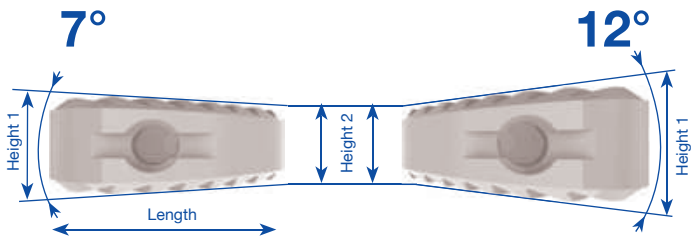
| 1901122211 | Adonis ALIF Ti 32x22x11 7° | | | 11 | 8.3 | |
| 1901122213 | Adonis ALIF Ti 32x22x13 7° | | | 13 | 10.3 | |
| 1901122215 | Adonis ALIF Ti 32x22x15 7° | | | 15 | 12.3 | |
| 1901162211 | Adonis-ALIF Ti 32x22x11 12° | 22 | 32 | 11 | 6.3 | 12° |
| 1901162213 | Adonis-ALIF Ti 32x22x13 12° | | | 13 | 8.3 | |
| 1901162215 | Adonis-ALIF Ti 32x22x15 12° | | | 15 | 10.3 | |
| 1901162217 | Adonis-ALIF Ti 32x22x17 12° | | | 17 | 12.3 | |

## Avantgarde
PEEK

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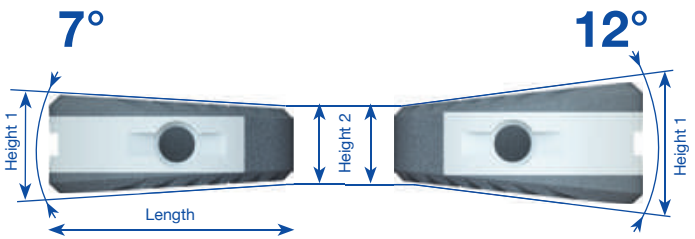
| 1902112211 | Adonis ALIF PEEK 32x22x11 7° | | | 11 | 8.3 | |
| 1902112213 | Adonis ALIF PEEK 32x22x13 7° | | | 13 | 10.3 | |
| 1902112215 | Adonis ALIF PEEK 32x22x15 7° | | | 15 | 12.3 | |
| 1902152211 | Adonis ALIF PEEK 32x22x11 12° | 22 | 32 | 11 | 6.3 | 12° |
| 1902152213 | Adonis ALIF PEEK 32x22x13 12° | | | 13 | 8.3 | |
| 1902152215 | Adonis ALIF PEEK 32x22x15 12° | | | 15 | 10.3 | |
| 1902152217 | Adonis ALIF PEEK 32x22x17 12° | | | 17 | 12.3 | |

## Exclusive
R-PEEK-Ti

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| 1903142211 | Adonis ALIF R-PEEK-Ti 32x22x11 7° | | | 11 | 8.3 | |
| 1903142213 | Adonis ALIF R-PEEK-Ti 32x22x13 7° | | | 13 | 10.3 | |
| 1903142215 | Adonis ALIF R-PEEK-Ti 32x22x15 7° | | | 15 | 12.3 | |
| 1903172211 | Adonis ALIF R-PEEK-Ti 32x22x11 12° | 22 | 32 | 11 | 6.3 | 12° |
| 1903172213 | Adonis ALIF R-PEEK-Ti 32x22x13 12° | | | 13 | 8.3 | |
| 1903172215 | Adonis ALIF R-PEEK-Ti 32x22x15 12° | | | 15 | 10.3 | |
| 1903172217 | Adonis ALIF R-PEEK-Ti 32x22x17 12° | | | 17 | 12.3 | |

## Instruments
ADONIS®-ALIF

| Item no. | Name | Image |
|---|---|---|
| 1901011009<br>1901011011<br>1901011013<br>1901011015 | ALIF Trial 32x22x09 7°<br>ALIF Trial 32x22x11 7°<br>ALIF Trial 32x22x13 7°<br>ALIF Trial 32x22x15 7° |  |
| 1901011111<br>1901011113<br>1901011115<br>1901011117 | ALIF Trial 32x22x11 12°<br>ALIF Trial 32x22x13 12°<br>ALIF Trial 32x22x15 12°<br>ALIF Trial 32x22x17 12° |  |
| 1901011001 | ALIF Inserter |  |
| 1701010600 | Extractor Handle |  |

The implant surface has major importance for anchoring the implant and for implant compatibility at the interface implant / adjacent tissue. The success and speed of osseointegration are significantly influenced by the surface of the implant. Using an ideal implant surface, the biological responses between implant and bone can be optimised, and thus an earlier functional loading of implants can be achieved.

Immediately after introducing the implant, complex biological processes are induced between the surrounding tissue and the implant surface. The bone and wound healing can be divided into three phases.

During the first and most important healing phase, the initial blood contact forms a fibrin network (Fig. 13) on the implant surface. This is associated with an aggregation of thrombocytes and blood coagulation. The resulting blood coagulum is an important matrix for the invasion and migration of osteogene cells to the implant surface and thereby plays a deciding role for wound healing and osseointegration.

The osteogene cells differentiate at the implant surface and activate the generation of new bone by forming a bone-specific extracellular matrix (collagen) on the implant surface (Fig. 16).

On the next step, a mineralised boundary surface is formed. This is equivalent to a thin collagen-free layer on the outer side of an osteon in the natural bone tissue.

In the third, slow-healing phase, the bone is reconstructed until reaching its final load-bearing characteristics.

The time required for the three phases of healing time is referred to as osseointegration time and describes the time in which the bone substance links to the implant permanently and with sufficient strength.

ADONIS® Exclusive has an optimised and reproducible surface topography. The relation between surface topography and successful osseointegration has been studied intensively in the past three decades and is well described today.

Besides the surface-topography, the osseointegration of the implant can be improved through chemical coatings on the surface. The moderately rough surface (Fig. 14 - “HENIAPORE-K”) of ADONIS® Exclusive leads to a better bone adherence. HenniaPore has been developed in order to optimise the implant surface so as to promote rapid and postoperative adherence of the young bone (Fig. 15). A review of clinical and animal studies by Shalabi et Alvi affirms this statement.

The vacuum-plasma injection procedure used for ADONIS® Exclusive is currently the most successful method for creating biocompatible layers. Due to this very extensive manufacturing process, an optimum wettable implant surface is retained while preserving the same surface topography.

Osseointegration can be accelerated through this improved wettability and a greater implant stability is attained in the early phase of osseointegration, as revealed in animal studies and clinical data.

This method is proven worldwide for hip, knee, shoulder, wrist and tooth implants. Spinal application thus appears to be logical.

Nowadays, commercially successful implant systems usually have an optimised and reproducible surface topography. In contrast to this, the surface of ADONIS® Exclusive also has an optimised and reproducible surface chemistry, which leads to improved wetting and hence more homogeneous blood contact with the implant

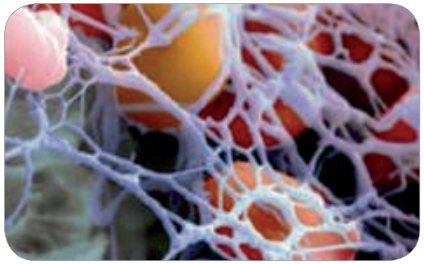


Fig. 13

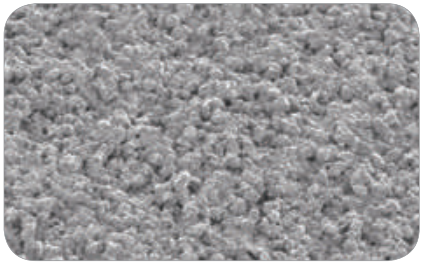


Fig. 14

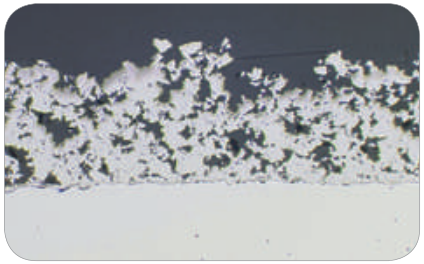


Fig. 15

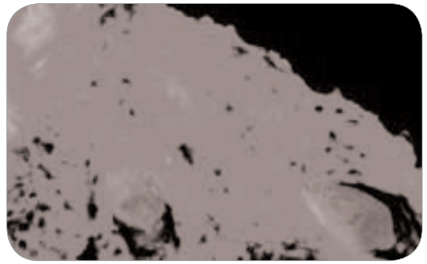


Fig. 16

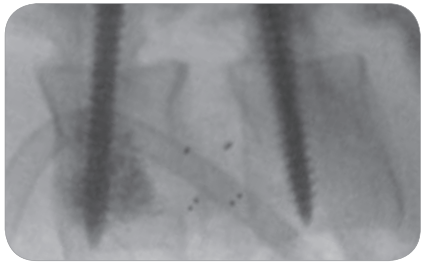
surface.

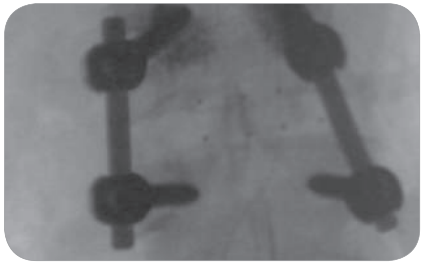
**Summary:**
The long-term success of an implant therapy concept is determined by multiple factors, but mainly by the bone density of the implant bed, the implant design and the implant surface. The composition, roughness and topography of the implant surface at the interface play an important role in primary stability and safe osseointegration. Rough implant surfaces will influence and stimulate the cellular activity of surrounding bony structures. Cell proliferation and cell differentiation, matrix synthesis and production of “tissue growth factors” are encouraged and lead to a dense bone-implant connection.

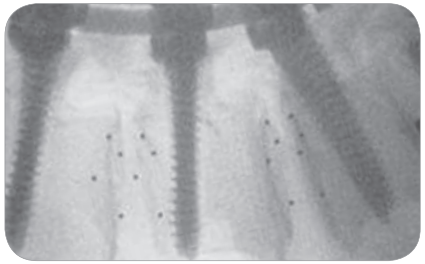
Specific surface roughness on the implant surface will encourage the regeneration potential at the interface and thus the clinical implant fixation.

Compared to machine-processed implant surfaces, the moderately rough surface (Fig. 14 - HENIAPORE-K”) of ADONIS® Exclusive exhibits denser bone apposition with significantly increased withdrawal force (removal load) and an extremely high coefficient of friction for primary stabilisation.

This results in an accelerated osseointegration of these implants and the possibility of an earlier exposure.







**General conditions for use**

- We recommend that you do not use ADONIS® in combination with implants from another source or another manufacturer. HumanTech Germany GmbH shall not be liable if this recommendation is not followed.

- Never reuse the implants. Even if the implant appears to be intact following revision, alterations within the implant or minute defects resulting from the loading and stressing to which the implant has been subjected can cause the implant to break.

- Implants from the ADONIS® range have a limited useful life. The activities and physical activity of the patient have a significant influence on this useful life. Patients must be informed that every activity increases the risk of loss, bending or breakage of the implant components. Informing patients about limitations to their activities in the postoperative phase and postoperatively monitoring patients are crucial factors in assessing the development of the fusion and the condition of the implant. Even when permanent bone fusion has occurred implant components can still bend, break or loosen. Patients must therefore be informed that implant components may also bend, break or loosen even if they comply with the restriction in their activities.
- If an implant does break, the doctor must decide whether a revision of the implant should be performed, taking into account the well-being of the patient and the risks involved.

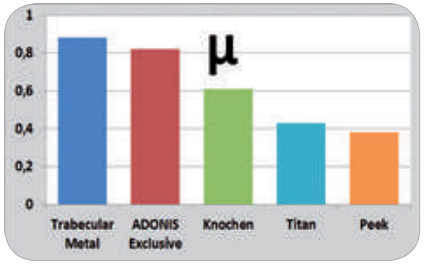
- The instructions in the Surgical Technique operation manual must be followed at all times.

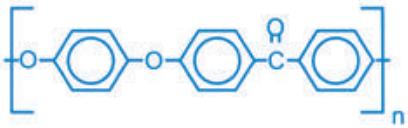
- Proceed with extreme caution in the region of the spinal cord and the roots of the nerves, since damage to the nerves can lead to the impairment of neurological functions.

- Breakage, slippage or incorrect use of the instruments or implants can injure the patient or the operating staff.

- Do not use bone cement, as this material makes the removal of the components difficult or impossible. The heat produced by the hardening process can damage or deform the PEEK implants.

- Handle removed implants in such a way that their reuse is not possible.



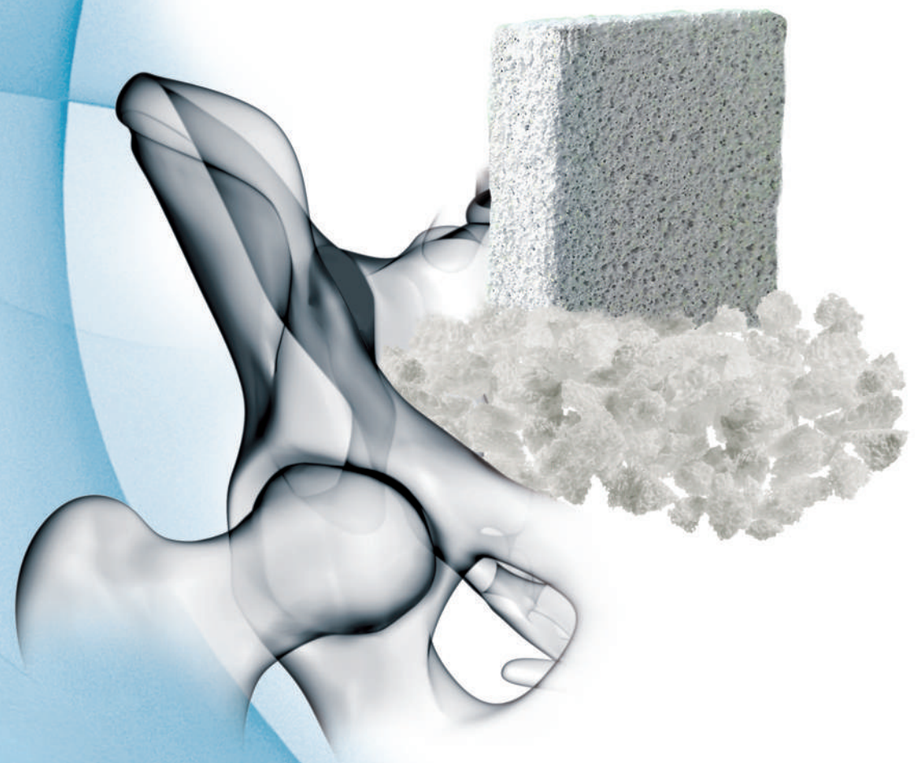



## Artosal® Blocks

| SIZE | QUANTITY | ART.-NO. |
|---|---|---|
| 10 x 10 x 10 mm | 1 | 248022 |
| 10 x 10 x 20 mm | 1 | 248023 |
| 10 x 30 x 30 mm | 1 | 248029 |
| 20 x 20 x 20 mm | 1 | 248030 |

## Artosal® Granules

| GRAIN SIZE | ART.-NO. |
|---|---|
| 5 cc (1-4 mm) | 248011 |
| 10 cc (1-4 mm) | 248012 |
| 15 cc (1-4 mm) | 248013 |
| 20 cc (1-4 mm) | 248014 |
| 30 cc (1-4 mm) | 248016 |

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Fax +31 24 371 5253

**customerservice@emcm.com**
**www.emcm.com**



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WP 3F0010 EN / 1511


Artosal®
• Resorbable Synthetic Bone Substitute

# Artosal®

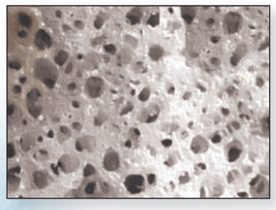
**Artosal® is a fully synthetic osteoconductive bone substitute for reconstruction of aseptic bone defects that shows a controlled resorption. Due to its ultra porous and highly interconnected pore matrix it offers a similar strength to cancellous bone and supports the remodelling of the new natural bone.**

### Benefits

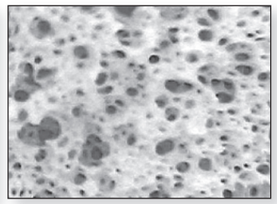
- Osteoconductive and fully biocompatible
- Very similar to the mineral component of human bone due to composition of 60 % hydroxyapatite (HA) and 40 % β-tricalcium phosphate (β-TCP)
- Ultra porous, 200-800 µm pore size range (average 250 – 400 µm)
- Ultra highly interconnected pores are similar to cancellous bone for rapid and unrestricted bone ingrowth
- Microporosity allows nutrient transfer
- Controlled resorption after 1-2 years (depending upon patient and defect location)
- Resorption byproducts encourage osteoblast formation & ingrowth
- Easy to use, no chemical mixing of components
- Adjustable to defect size with standard surgical instruments
- Synthetic and fully reproducible, reliable and consistent performance to reduce / eliminate need for autograft
- Can be mixed with bone marrow aspirate or platelet concentrate to provide an additional biological boost from associated growth factors
- Compositions of HA and TCP are successfully used in more than 25 years

## Resorbable synthetic bone substitute with almost identical set-up and structure of the human bone

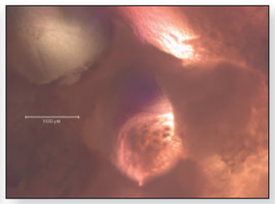
The fully interconnected pore structure is nearly identical with the human cancellous bone and provides an ideal environment for the ingrowth of new bone. Over 80 % porosity allows rapid bone ingrowth throughout the interconnected pore system.
Artosal® provides support without significantly limiting natural bone density. The microporosity within the Artosal® structure assists the supply of the new bone with essential nutrients.



Human cancellous bone



Artosal®



Osteoconduction with bone radiating through pores to the centre of the implant

### Indications

Artosal® can be used for many not load bearing indications of aseptic bone reconstruction in the fields of traumatology, orthopaedics, spine and neurosurgery by supporting the ingrowth of adjacent viable bone in defects that are not intrinsic to the stability of the bone structure. These indications can be:

- Filling of defects of pelvis, long bones and extremities
- Filling of bone defects in epiphyseal and diaphyseal simple and comminuted fractures
- Filling of bone defects of the acetabulum on change of prosthesis
- Filling after removal of osteosynthesis materials
- Filing of bone defects with delayed or non-union pseudarthrosis, arthrodesis and osteotomies
- Filling of defects caused by excision of benign bones
- Filling of bone cysts
- Lumbar spinal fusion

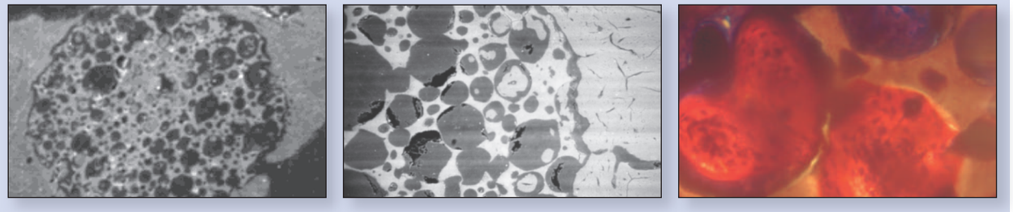
### Publications / Clinical Studies

The biocompatibility and clinical efficacy of HA and TCP as bone substitute materials is supported by over 3,000 publications and over 500 clinical studies with more then 25 years of successful use.
Artosal® has proven biocompatibility and osteoconductivity. Studies show that Artosal® implanted both in cancellous bone and cortical bone gives excellent osseointegration with rapid bone penetration through the core of the implant.

**Animal Results**

## In vivo determination of the biocompatibility of calcium phosphate bioceramics implanted in a non-healing mandibular ramus model:

The aim of this consultancy was to investigate the response of bone to porous ceramic material HA/TCP (Artosal®) in vivo using a non-healing model. The jaw model in the rat mandible has been well documented, consisting of a full thickness defect in the ramus of the mandible. A standardised full thickness 'non-healing' defect was created from an extra-oral approach in the left mandibular ramus of 21 male Wister Rats, aged between 3 and 4 months (weight 450 to 500 g). The animals were divided equally into groups according to the treatment they received; defects were left to heal unaided (control) or received implantation of HA+bTCP (Artosal®) discs.



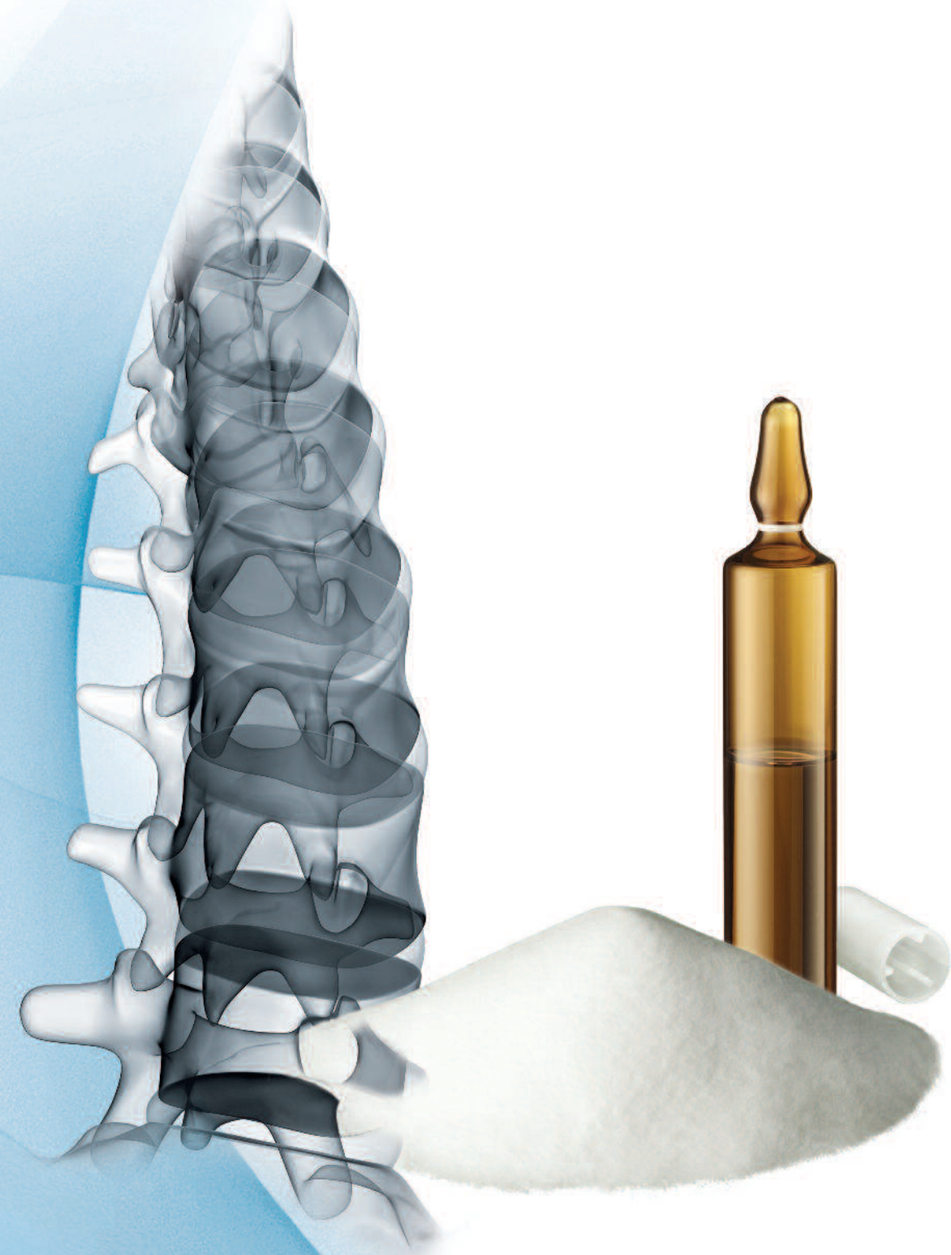
Detail from two different specimens showing new bone infiltrating into pores.

**Conclusions**

New bone failed to develop in the control defects. The HA/bTCP (Artosal®) was osteoconductive with clear evidence of new bone formation in the larger pores of both materials. There was evidence of good osseointegration of HA/bTCP (Artosal®). Qualitatively at 6 weeks healing there was good bone infiltration into HA/bTCP (Artosal®). The hard and soft tissues accepted the presence of HA/bTCP (Artosal®) with no evidence of any adverse effect. There was no evidence of any fibrous encapsulation of HA/bTCP (Artosal®).

## BonOs Inject®

| PACKAGING SIZE | | ART.-NO. |
|---|---|---|
| 1 x 24 g | CE-Version | 01-0310 |
| 1 x 24 g | US-Version | 01-0309 |



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Fax +49 6071 929-100

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WM 2007-02 / 0912

BonOs® Inject

• Bone Cement for Spinal Applications

# BonOs® Inject

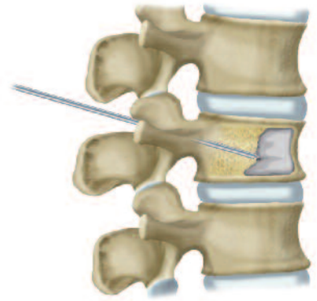
PMMA is been used in orthopedics for almost 50 years. Within that time the indication fields have been extended step by step until in the 80's PMMA cements were applied in spinal surgery, too. There, they serve to stabilize and fill cavities of erected vertebral bodies. For these specific indications BonOs® Inject was developed.

## BonOs® Inject fulfills all requirements for bone cements in spinal surgery:

- Suitable viscosity for Vertebroplasty and Kyphoplasty
- Short mixing time, long application time
- Rapid application viscosity due to improved cohesion
- High radiodensity with 45% $ZrO_2$
- Excellent mechanical properties
- Low hardening temperature of about 70°C

## Initially high viscosity for rapid application due to improved cohesion

The chemical composition of the polymers ensures a high initial cohesion and therefore reduces the risk of cement leakage. After a short waiting time the cement attains an ideal viscosity for application. That can be used for Vertebroplasty and Kyphoplasty.



Example of a cemented vertebra

## Chemical composition

| Powder (24 g) | |
|---|---|
| Poly (MMA) | 10,95 g |
| Poly (MA, MMA) | 1,75 g |
| Zirconium dioxid | 10,80 g |
| Benzoyl peroxid | 0,50 g |

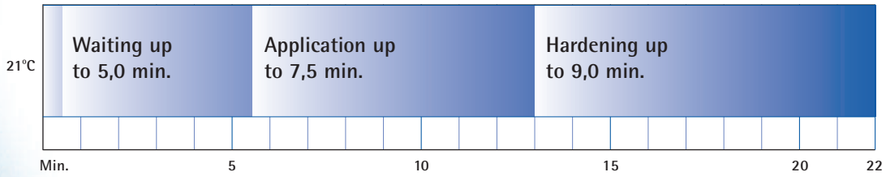
| Liquid (10 ml) | |
|---|---|
| MMA | 9,93 ml |
| Dimethyl-p-toluidine | 0,07 ml |
| Hydroquinone | 60 ppm |

## Long application time

Both components dash quickly to a homogenous paste with the right viscosity for percutaneous injection. After a short mixing time the surgeon has a long application time to apply BonOs® Inject without time pressure.

| Max. Zeit [Min.] at 21°C | |
|---|---|
| Mixing | 0,5 |
| Waiting | 5,0 |
| Application | 7,5 |
| Hardening | 9,0 |

Temperature-Time Chart (e.g. 21°C)*




* For further information see the Instructions for Use

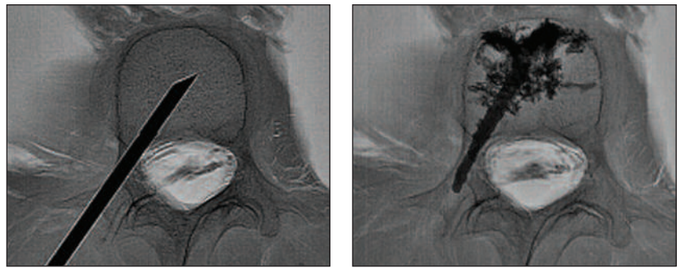
**Test conditions**

Application needle: ø 3 mm, length 120 mm
Syringe capacity: 1 ml

## High radiopacity

The addition of a high amount of zirconium dioxide ($ZrO_2$) allows an optimal X-ray visualization of BonOs® Inject for a safe use. Zirconium dioxide has a positive influence on the mechanical stability.

**X-ray Images Cadaver Tests**

## Good mechanical properties

The chemical composition of BonOs® Inject guarantees optimized mechanical properties which exceed the respective requirements of the ISO 5833 standard.

| | ISO 5833 | BonOs® Inject |
|---|---|---|
| Compression strength [MPa] | ≥ 70 | 122 ± 1,5 |
| E-modulus [MPa] | ≥1800 | 4240 ± 177 |
| Bending strength [MPa] | ≥50 | 70 ± 5,4 |

www.samaysurgical.com

Mfg. : Orthopedic Implant & Instruments

# SAMAY Surgical

An **ISO 13485:2003**
Certified Company

CE
0801-1

# Product Catalogue

## 4.0 mm Pediatric Mono Screw
(Stainless Steel & Titanium)

Note: Define Code for
S.S. SS 401 & Titanium TT 401

| Code No. | Length |
|---|---|
| SS 401-120 | 20 mm |
| SS 401-125 | 25 mm |
| SS 401-130 | 30 mm |
| SS 401-135 | 35 mm |
| SS 401-140 | 40 mm |

## 5.0 mm Mono Screw
(Stainless Steel & Titanium)

Note: Define Code for
S.S. SS 402 & Titanium TT 402

| Code No. | Length |
|---|---|
| SS 402-130 | 30 mm |
| SS 402-135 | 35 mm |
| SS 402-140 | 40 mm |
| SS 402-145 | 45 mm |
| SS 402-150 | 50 mm |

## 6.0 mm Mono Screw
(Stainless Steel & Titanium)

Note: Define Code for
S.S. SS 403 & Titanium TT 403

| Code No. | Length |
|---|---|
| SS 403-130 | 30 mm |
| SS 403-135 | 35 mm |
| SS 403-140 | 40 mm |
| SS 403-145 | 45 mm |
| SS 403-150 | 50 mm |

## 4.0 mm Pediatric Poly Screw
(Stainless Steel & Titanium)

Note: Define Code for
S.S. SS 404 & Titanium TT 404

| Code No. | Length |
|---|---|
| SS 404-120 | 20 mm |
| SS 404-125 | 25 mm |
| SS 404-130 | 30 mm |
| SS 404-135 | 35 mm |
| SS 404-140 | 40 mm |

## 5.0 mm Poly Screw
(Stainless Steel & Titanium)

Note: Define Code for
S.S. SS 405 & Titanium TT 405

| Code No. | Length |
|---|---|
| SS 405-130 | 30 mm |
| SS 405-135 | 35 mm |
| SS 405-140 | 40 mm |
| SS 405-145 | 45 mm |
| SS 405-150 | 50 mm |

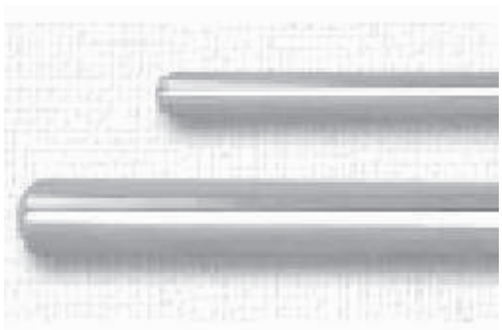
## 6.0 mm Poly Screw
(Stainless Steel & Titanium)

Note: Define Code for
S.S. SS 406 & Titanium TT 406

| Code No. | Length |
|---|---|
| SS 406-130 | 30 mm |
| SS 406-135 | 35 mm |
| SS 406-140 | 40 mm |
| SS 406-145 | 45 mm |
| SS 406-150 | 50 mm |

## Connecting Road
(Stainless Steel & Titanium)

Note: Define Code for
S.S. SS 427 & Titanium TT 427



| Length | 20 mm Dia. Code No. | 30 mm Dia. Code No. | 40 mm Dia. Code No. | 50 mm Dia. Code No. |
|---|---|---|---|---|
| 50 mm | SS 427-201 | SS 427-301 | SS 427-401 | SS 427-501 |
| 75 mm | SS 427-202 | SS 427-302 | SS 427-402 | SS 427-502 |
| 80 mm | SS 427-203 | SS 427-303 | SS 427-403 | SS 427-503 |
| 100 mm | SS 427-204 | SS 427-304 | SS 427-404 | SS 427-504 |
| 120 mm | SS 427-205 | SS 427-305 | SS 427-405 | SS 427-505 |
| 125 mm | SS 427-206 | SS 427-306 | SS 427-406 | SS 427-527 |
| 150 mm | SS 427-207 | SS 427-307 | SS 427-407 | SS 427-507 |
| 200 mm | SS 427-208 | SS 427-308 | SS 427-408 | SS 427-508 |
| 250 mm | SS 427-209 | SS 427-309 | SS 427-409 | SS 427-509 |
| 300 mm | SS 427-210 | SS 427-310 | SS 427-410 | SS 427-510 |
| 480 mm | SS 427-211 | SS 427-311 | SS 427-411 | SS 427-511 |

## Anterior Cervical Plate
(Titanium)

| Code No. | Length |
|---|---|
| SS 429-020 | 20 mm |
| SS 429-025 | 25 mm |
| SS 429-030 | 30 mm |
| SS 429-035 | 35 mm |
| SS 429-040 | 40 mm |
| SS 429-045 | 45 mm |
| SS 429-050 | 50 mm |
| SS 429-055 | 55 mm |
| SS 429-060 | 60 mm |
| SS 429-065 | 65 mm |
| SS 429-070 | 70 mm |
| SS 429-075 | 75 mm |
| SS 429-080 | 80 mm |
| SS 429-085 | 85 mm |
| SS 429-090 | 90 mm |
| SS 429-095 | 95 mm |
| SS 429-100 | 100 mm |
| SS 429-105 | 105 mm |
| SS 429-110 | 110 mm |

## Cage
(Stainless Steel & Titanium)

Note: Define Code for
S.S. SS 428 & Titanium TT 428

| Length | 10 mm Dia. Code No. | 12 mm Dia. Code No. | 14 mm Dia. Code No. | 16 mm Dia. Code No. | 18 mm Dia. Code No. | 20 mm Dia. Code No. | 22 mm Dia. Code No. | 24 mm Dia. Code No. |
|---|---|---|---|---|---|---|---|---|
| 20 mm | SS 428-120 | SS 428-220 | SS 428-320 | SS 428-420 | SS 428-520 | SS 428-620 | SS 428-720 | SS 428-820 |
| 25 mm | SS 428-125 | SS 428-225 | SS 428-325 | SS 428-425 | SS 428-525 | SS 428-625 | SS 428-725 | SS 428-825 |
| 30 mm | SS 428-130 | SS 428-230 | SS 428-330 | SS 428-430 | SS 428-530 | SS 428-630 | SS 428-730 | SS 428-830 |
| 35 mm | SS 428-135 | SS 428-235 | SS 428-335 | SS 428-435 | SS 428-535 | SS 428-635 | SS 428-735 | SS 428-835 |
| 40 mm | SS 428-140 | SS 428-240 | SS 428-340 | SS 428-440 | SS 428-540 | SS 428-640 | SS 428-740 | SS 428-840 |
| 45 mm | SS 428-145 | SS 428-245 | SS 428-345 | SS 428-445 | SS 428-545 | SS 428-645 | SS 428-745 | SS 428-845 |
| 50 mm | SS 428-150 | SS 428-250 | SS 428-350 | SS 428-450 | SS 428-550 | SS 428-650 | SS 428-750 | SS 428-850 |

## 4.0 mm Bone Screw for Anterior Cervical Plate
(Titanium)

| Code No. | Length |
|---|---|
| SS 430-010 | 10 mm |
| SS 430-012 | 12 mm |
| SS 430-014 | 14 mm |
| SS 430-016 | 16 mm |
| SS 430-018 | 18 mm |
| SS 430-020 | 20 mm |
| SS 430-022 | 22 mm |
| SS 430-024 | 24 mm |

## 4.5 mm Mono Screw Single Lock
(Stainless Steel & Titanium)

Note: Define Code for
S.S. SS 432 & Titanium TT 432

| Code No. | Length |
|---|---|
| SS 432-015 | 15 mm |
| SS 432-020 | 20 mm |
| SS 432-025 | 25 mm |
| SS 432-030 | 30 mm |
| SS 432-035 | 35 mm |

## 6.5 mm Mono Screw Single Lock
(Stainless Steel & Titanium)

Note: Define Code for
S.S. SS 434 & Titanium TT 434

| Code No. | Length |
|---|---|
| SS 434-030 | 30 mm |
| SS 434-035 | 35 mm |
| SS 434-040 | 40 mm |
| SS 434-045 | 45 mm |
| SS 434-050 | 50 mm |
| SS 434-055 | 55 mm |

## Lock Screw for Anterior Cervical Plate
(Titanium) Code No. TT 431-001

## 5.5 mm Mono Screw Single Lock
(Stainless Steel & Titanium)

Note: Define Code for
S.S. SS 433 & Titanium TT 433

| Code No. | Length |
|---|---|
| SS 433-030 | 30 mm |
| SS 433-035 | 35 mm |
| SS 433-040 | 40 mm |
| SS 433-045 | 45 mm |
| SS 433-050 | 50 mm |
| SS 433-055 | 55 mm |

## 4.5 mm Poly Screw Single Lock
(Stainless Steel & Titanium)

Note: Define Code for
S.S. SS 435 & Titanium TT 435

| Code No. | Length |
|---|---|
| SS 435-015 | 15 mm |
| SS 435-020 | 20 mm |
| SS 435-025 | 25 mm |
| SS 435-030 | 30 mm |
| SS 435-035 | 35 mm |

SURGICAL
INNOVATIONS

TECHNICAL DATA SHEET
**MIS Z-PEDICLE SCREW SYSTEM**



## Instrument Set

The MIS Z-Pedicle Screw System offers surgeons an ideal solution for their indication specific needs.

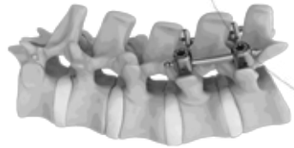
* Only one basic instrument set
* High versatility
* Intraoperative controll features
* Significant timesaver on logistics & reprocessing

## Patented Pedicle Screw

The innovative screw design offers the possibility of a direct manipulation without an assembly of additional instruments.

* Easy handling
* Reduces surgical steps
* Uniplanar screw for fracture and deformity treatment

Z-MEDICAL
SURGICAL
INNOVATIONS



## Indication

The multifunctional system enables surgeons to efficiently and cost effectively address the most common pathologies.

* Approved for degenerative, trauma, tumor and deformity application
* Ideal treatment option for spondylolisthesis

## Sterile Packaging

All implants are single sterile packaged and ready for surgery.

* Maximizing safety for surgeons and patients
* No contamination and damages to implants
* Full traceability of implants

## MIS Z-Pedicle Screw

| | |
|---|---|
| Screw [Ø]: | 5 / 6 / 7 / 8 mm |
| Length [mm]: | 35 / 40 / 45 / 50 / 55 mm |
| Rod [Ø]: | 5.5 mm |

Axialities:

* Polyaxial (PA)
* Quattroaxial (QA) for fractures & spondylolisthesis
* Quattroaxial-trans. (QA trans) for deformity treatments
* Monoaxial (MA)

This flyer is just for understanding the specific product features. Please refer to the MIS Z-Pedicle Screw Instruction for Use and Surgical Technique for complete description, indication and warnings!

**Z-Medical | Contact**

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Web: www.z-medical.de



05.10.2016
Rev. 1
Art.Nr.: Y30 012

## Innovative Implant Design

**Multifunctional Lengthening Shaft**

› Ø 12mm

**Pre-Assembled Ini (Set-Screw)**

› No cross-threading
› Prevents tulip splay

**Reduction Thread**

› 45mm

**Patented SnapOff-Technique**

› Rigid connection between the shaft and the implant
› Burr-free separation

## Screw Design

**Patented Screw(head)design**

› 4 axialities

**Double thread with high pitch**

› Faster insertion, 6mm per rotation
› Strong purchase in the bone

**Cannulated and fenestrated**

› Guided MIS screw insertion
› Controlled cement augmentation

**Thread features**

› Self-drilling & self-tapping
› Fast initial bone grip

## Quattroaxial Screw

The Quattroaxial Screw allows shorter instrumentation and simplifies reposition.


**Degree of freedom:**

› Medial-Lateral: moving freely
› Cranio-Caudal: blocked

**Advantages vs. Polyaxial Screw:**

› No anterior height loss due to 2-3 times higher angular stability

› No sliding of screw head due to the tongue and groove feature

**Advantages vs. Monoaxial Screw:**

› Facilitates the rod insertion and minimizes undesired tension

## Reduction / Reposition

› Easy alignment after surgical reduction of spondylolisthesis

› Without additional instruments

› Directly achieved with the pre-assembled set-screw and the long reduction thread

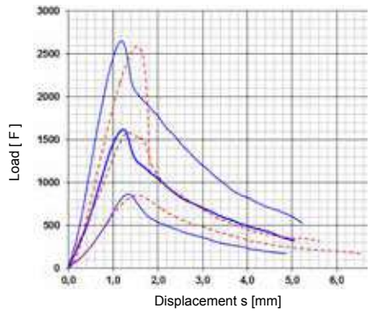
## Thread Design

**Advantages:**

› The multi-conical double thread design increases stability and pullout resistance in the pedicle and offers ease of insertion.

› The conical outlet section of the core additionally stabilises at the pedicle entry and strengthens the purchase by the compression of the bone.

## Pullout Strength

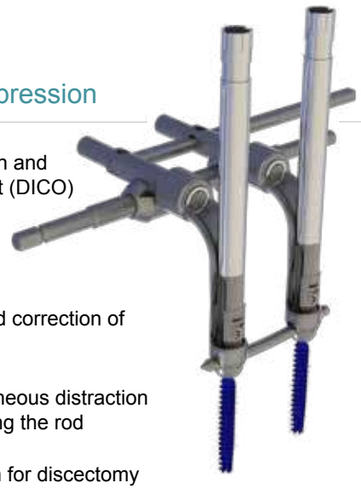




TD1= Z-Medical thread design, self-drilling and -tapping
TD2= Competitor thread design of a common screw with cortical and cancellous threads sections.

Results are based on mechanical tests performed by an independent testing laboratory, the Steinbeis Transfer Center BWF Esslingen. Tested according to ASTM F1798-13.

| Manufacturer | Foam density [ PCF ] | Maximum Pullout Load $F_{max}$ [N] |
|---|---|---|
| Z-Medical $TD_1$ | 10 | 867 |
| | 15 | 1620 |
| | 20 | 2652 |
| Competitor $TD_2$ | 10 | 853 |
| | 15 | 1588 |
| | 20 | 2590 |

## Distraction / Compression



The universal distraction and compression instrument (DICO) enables:

› A direct and controlled correction of complex fractures

› An open and percutaneous distraction and compression along the rod

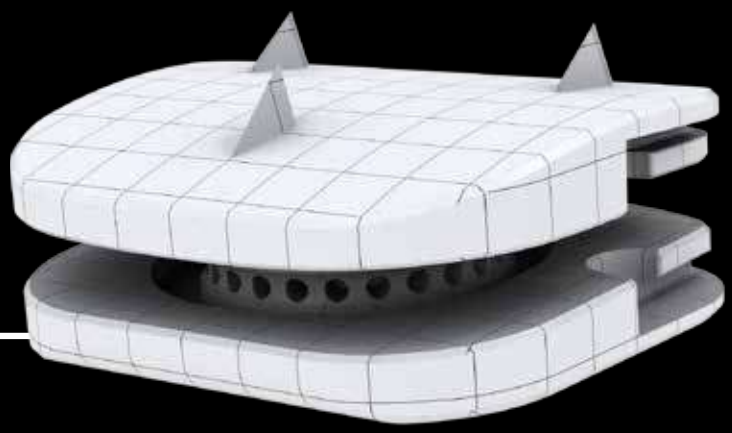
› Segmental distraction for discectomy and/ or insertion of an interbody device

› Same approach as MIS screw, application via the lengthening shaft

BAGUERA® C

BY SPINEART

# CERVICAL DISC PROSTHESIS



# CONTENT

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INSTRUMENT SET **PAGE 08**

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SURGICAL TECHNIQUE **PAGE 10**

# CONCEPT AND DESIGN

Powered in 2006 by a creative and pioneer team, BAGUERA®C was inspired by the black panther of the "Jungle book": black and elegant, agile but discret, mature while irresistible.

The goal at this time was to replace the disc function and to drastically simplify the existing technologies in motion preservation. After several years of usage and clinical follow up, BAGUERA®C is still innovative while clinically validated, and is now a reference in the cervical arthroplasty segment.

BAGUERA®C is a cutting-edge device that respects Spineart's philosophy, Quality, Innovation and Simplicity.

## AT A GLANCE

**GUIDED MOBILE NUCLEUS**

**ANATOMICAL DESIGN**

**LIMITED MRI ARTIFACT**

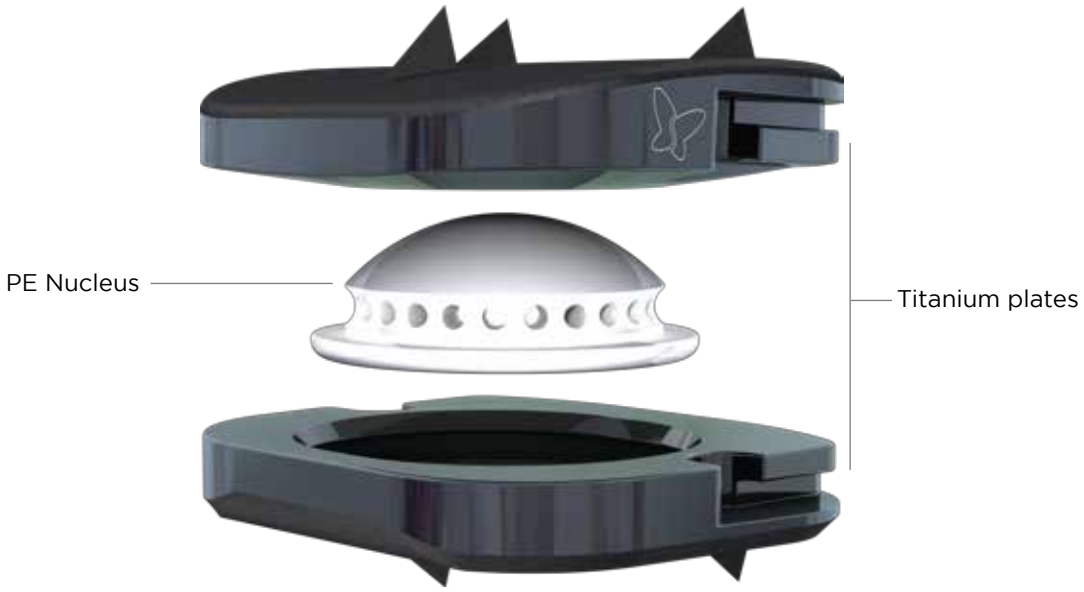
**RADIOLUCENT HOLDER**

## INDICATIONS

The disc prosthesis BAGUERA®C is intended as a replacement for a degenerated cervical disc.

The BAGUERA®C range is indicated for patients presenting with the following pathologies from C3 to C7 : Cervical hernia / Cervicarthrose / Degenerative disc disease.

# IMPLANTS




| REFERENCES | |
|---|---|
| **Heights** | **Small : 13x16mm** |
| 5mm | CDP-TI 13 05-S |
| 6mm | CDP-TI 13 06-S |
| 7mm | CDP-TI 13 07-S |

| **Heights** | **Medium : 14x17mm** |
|---|---|
| 5mm | CDP-TI 14 05-S |
| 6mm | CDP-TI 14 06-S |
| 7mm | CDP-TI 14 07-S |

| REFERENCES | |
|---|---|
| **Heights** | **Large : 16x18mm** |
| 5mm | CDP-TI 16 05-S |
| 6mm | CDP-TI 16 06-S |
| 7mm | CDP-TI 16 07-S |

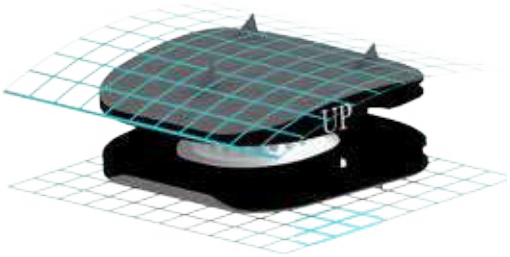
# TECHNICAL FEATURES

## GUIDED MOBILE NUCLEUS

- The guided mobile PE nucleus is designed to prevent excessive constraints on the facet joints. It allows 6 degrees of freedom.

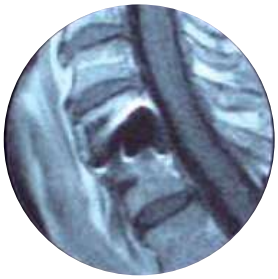
## ANATOMICAL DESIGN

- The sloping anatomical design of the plates optimizes the fit between the device and the disc space, and maximizes the endplate coverage.



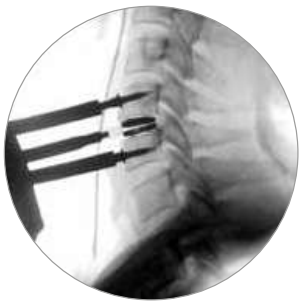

## LIMITED MRI ARTIFACT

- The titanium plates, coated with DIAMOLITH® reduce artifacts under MRI for a better postoperative control.



## RADIOLUCENT HOLDER

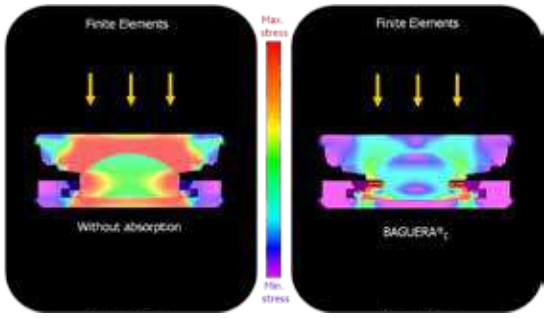
- The radiolucent holder allows for both verification of the anterior position of the device and confirmation of the fitting accuracy. Thanks to this holder, the device is delivered pre-assembled for better handling.



# TECHNICAL FEATURES

## SHOCK ABSORPTION

- The shape of the inferior plate and the PE nucleus are designed to enable absorption of shocks and vibrations.




## PRIMARY STABILITY

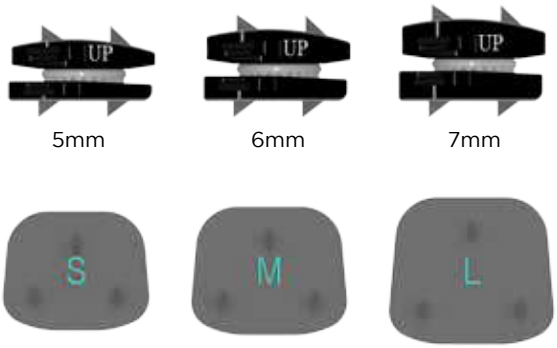
- The 3 upper and 3 lower fins as well as the porous titanium coating are designed for primary and secondary stability.


## COMPACT SET

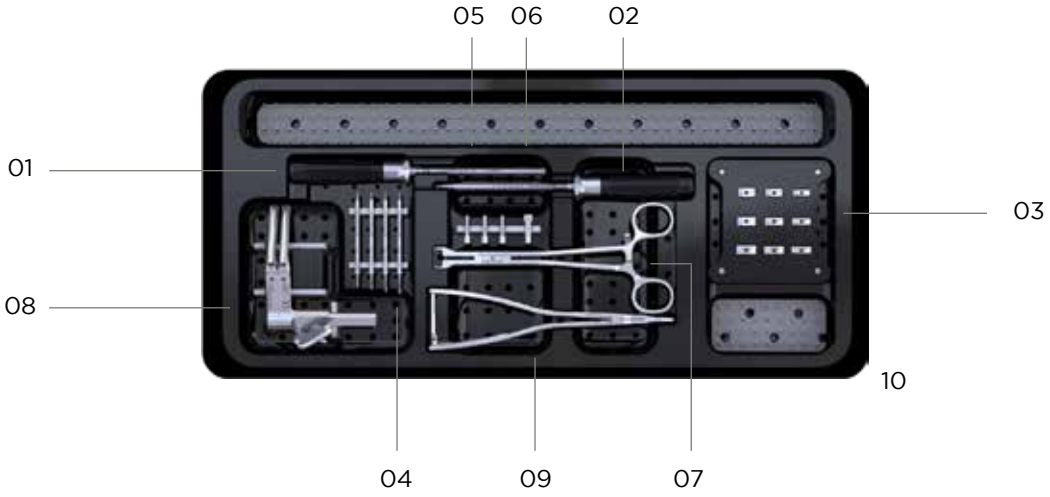
- The set includes 4 instruments, trials, and a lockable cervical system.

## COMPLETE RANGE

- The prosthesis is available in 3 footprints, small (13x16), Medium (14x17) and large (16x18) and 3 heights from 5 to 7 mm.



# INSTRUMENT SET




| # | DESCRIPTION | REFERENCE |
|---|---|---|
| 01 | SCREWDRIVER FOR PINS | CDP-IN 30 01-N |
| 02 | IMPLANT HOLDER | CDP-IN 00 01-N |
| 03 | TRIAL IMPLANTS | CDP-IN 13 05-N<br>CDP-IN 13 06-N<br>CDP-IN 13 07-N<br>CDP-IN 14 05-N<br>CDP-IN 14 06-N<br>CDP-IN 14 07-N<br>CDP-IN 16 05-N<br>CDP-IN 16 06-N<br>CDP-IN 16 07-N |
| 04 | PINS | CDP-IN 30 12-N<br>CDP-IN 30 14-N<br>CDP-IN 30 16-N<br>CDP-IN 30 18-N |

| # | DESCRIPTION | REFERENCE |
|---|---|---|
| 05 | NUT FOR PINS | CDP-IN 30 02-N |
| 06 | PUSHER | CDP-IN 00 03-N |
| 07 | EXTRACTOR | CDP-IN 00 02-N |
| 08 | ARTICULATED CERVICAL DISTRACTOR | CDP-IN 50 00-N |
| 09 | INTERSOMATIC DISTRACTOR | CDP-IN 00 04-N |
| 10 | INSTRUMENTS CONTAINER | CDP-BX 10 01-N |
| | **OPTION** | |
| | REVISION PINS | CDP-IN 40-12-N<br>CDP-IN 40-14-N<br>CDP-IN 40-16-N<br>CDP-IN 40-18-N |

# INSTRUMENTS

| | |
|---|---|
| PINS | CDP-IN 30 12-N to CDP-IN 30 18-N |

| | |
|---|---|
| ARTICULATED CERVICAL DISTRACTOR | CDP-IN 50 00-N |

| | |
|---|---|
| NUT FOR PINS | CDP-IN 30 02-N |

| | |
|---|---|
| SCREWDRIVER FOR PINS | CDP-IN 30 01-N |

| | |
|---|---|
| INTERSOMATIC DISTRACTOR | CDP-IN 00 04-N |

| | |
|---|---|
| TRIAL IMPLANTS | CDP-IN 13 05-N to CDP-IN 16 07-N |

| | |
|---|---|
| IMPLANT HOLDER | CDP-IN 00 01-N |

| | |
|---|---|
| EXTRACTOR | CDP-IN 00 02-N |

| | |
|---|---|
| PUSHER | CDP-IN 00 03-N |

# SURGICAL TECHNIQUE

## STEP **1**

PATIENT POSITIONING

Place the patient in a supine position on the operating table.

Be sure that the patient neck is in a normal, lordotic position. You can use a pillow.

## STEP **2**

INTERSOMATIC DISTRACTION

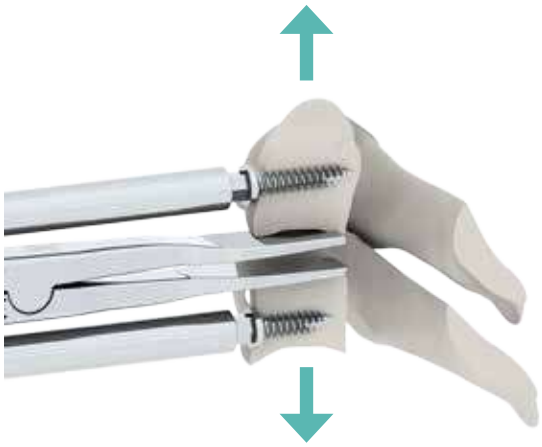
Place the cervical distractor pins parallel to the endplates on the midline.

Attach the nuts to the screwdriver and lock the pins with the nuts.

| INSTRUMENT | REFERENCE |
|---|---|
| PINS | CDP-IN 30 12-N to CDP-IN 3018-N |
| CERVICAL DISTRACTOR | CDP-IN 50 00-N |
| NUT FOR PINS | CDP-IN 30 02-N |
| SCREWDRIVER FOR PINS | CDP-IN 30 01-N |

# SURGICAL TECHNIQUE

## STEP **3**



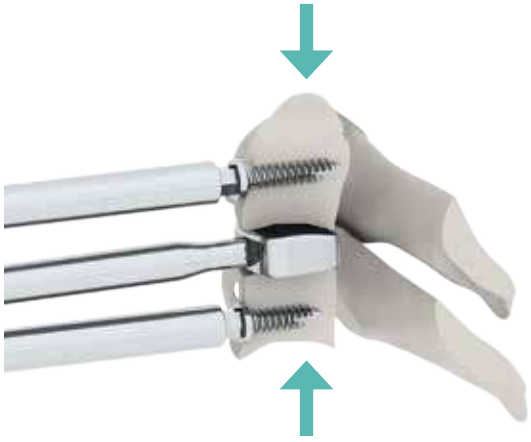
INTERSOMATIC DISTRACTION

Perform a complete discectomy.

Insert the intersomatic distractor until the posterior vertebral wall has been reached to distract in parallel.
Perform an x-ray control.
Support by blocking the distraction with the cervical distractor.

| INSTRUMENT | REFERENCE |
|---|---|
| INTERSOMATIC DISTRACTOR | CDP-IN 00 04-N |

## STEP **4**



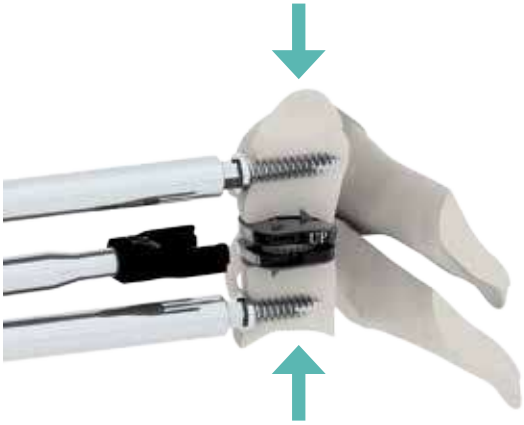
IMPLANT TRIALLING

Screw the trial implant on the implant holder and insert it into the disc space to determine the appropriate size of the device.
Carry-out an AP and lateral control.
Relax the distraction to verify the stability of the trial implant.
Distract again smoothly with the cervical distractor and take-out the trial implant.

| INSTRUMENT | REFERENCE |
|---|---|
| TRIAL IMPLANTS | CDP-IN 13 05-N to CDP-IN 16 07-N |
| IMPLANT HOLDER | CDP-IN 00 01-N |

# SURGICAL TECHNIQUE

## STEP **5**


PROSTHESIS INSERTION

Screw the implant holder on the pre-assembled prosthesis and insert the implant.

Carry-out an AP control to validate the correct positioning of the prosthesis.

The radiolucent «fork» permits a perfect visualization of the implant.

Relax the distraction.

Take-out the radiolucent “fork” by doing a slight lateral gesture with the implant holder.

OPTIONAL

- If necessary, a pusher can be attached to the implant holder to adjust the impaction of the prosthesis.
- The extractor is used to pull out the device.

| INSTRUMENT | REFERENCE |
|---|---|
| PUSHER | CDP-IN 00 03-N |
| EXTRACTOR | CDP-IN 00 02-N |

## FINAL CONSTRUCT

spineart.com

**SPINEART SA**
20 route de Pré-Bois
1215 Geneva 15
Switzerland

**SPINEART USA**
227 East 58th St. 2nd Floor
New York, NY 10022
United States of America

9200 Irvine Center Drive, Suite 150
Irvine, CA 92618
United States of America

SWISS MADE

0414-V2 ref. BAG-BR CE 31-E CE 1250

SURGICAL
INNOVATIONS

## Z-PEDICLE SCREWS, STERILE, TITANIUM
## Z-PEDIKELSCHRAUBEN, STERIL, TITAN

| Ø L. | Polyaxial 50° | Quattroaxial 50°/5° | Quattroaxial trans. 50°/5° | Monoaxial |
|---|---|---|---|---|
| 5 x 35 | A06 051 | A06 151 | A06 451 | A06 251 |
| 5 x 40 | A06 052 | A06 152 | A06 452 | A06 252 |
| 5 x 45 | A06 053 | A06 153 | A06 453 | A06 253 |
| 5 x 50 | A06 054 | A06 154 | A06 454 | A06 254 |
| 6 x 35 | A06 061 | A06 161 | A06 461 | A06 261 |
| 6 x 40 | A06 062 | A06 162 | A06 462 | A06 262 |
| 6 x 45 | A06 063 | A06 163 | A06 463 | A06 263 |
| 6 x 50 | A06 064 | A06 164 | A06 464 | A06 264 |
| 6 x 55 | A06 065 | A06 165 | A06 465 | A06 265 |
| 7 x 35 | A06 071 | A06 171 | A06 471 | A06 271 |
| 7 x 40 | A06 072 | A06 172 | A06 472 | A06 272 |
| 7 x 45 | A06 073 | A06 173 | A06 473 | A06 273 |
| 7 x 50 | A06 074 | A06 174 | A06 474 | A06 274 |
| 7 x 55 | A06 075 | A06 175 | A06 475 | A06 275 |
| 8 x 35 | A06 091 | A06 191 | A06 491 | A06 291 |
| 8 x 40 | A06 092 | A06 192 | A06 492 | A06 292 |
| 8 x 45 | A06 093 | A06 193 | A06 493 | A06 293 |
| 8 x 50 | A06 094 | A06 194 | A06 494 | A06 294 |
| 8 x 55 | A06 095 | A06 195 | A06 495 | A06 295 |

L. = screw length in mm
L. = Schraubenlänge in mm

Ø = diameter in mm
Ø = Durchmesser in mm

## Z-ROD Ø 5,5 mm, STERILE, TITANIUM
## Z-STAB Ø 5,5 mm, STERIL, TITAN

| L. lordotic / *lordotisch* | | L. straight / *gerade* | |
|---|---|---|---|
| 30 | A06 350 | 130 | A06 390 |
| 35 | A06 351 | 140 | A06 391 |
| 40 | A06 352 | 150 | A06 392 |
| 45 | A06 353 | 160 | A06 393 |
| 50 | A06 354 | 180 | A06 394 |
| 55 | A06 355 | 200 | A06 395 |
| 60 | A06 356 | 220 | A06 396 |
| 65 | A06 357 | 240 | A06 397 |
| 70 | A06 358 | 260 | A06 398 |
| 75 | A06 359 | 280 | A06 399 |
| 80 | A06 360 | 300 | A06 400 |
| 85 | A06 361 | | |
| 90 | A06 362 | | |
| 95 | A06 363 | | |
| 100 | A06 364 | | |
| 110 | A06 366 | | |
| 120 | A06 368 | | |

Note: Please note that the Ini is not available single sterile packged as all Z-Pedicle Screws have an Ini (set screw) already pre-assembled.
Bemerkung: Der Ini (Verschlußschraube) ist vormontiert und ist nicht einzeln verpackt erhältlich.

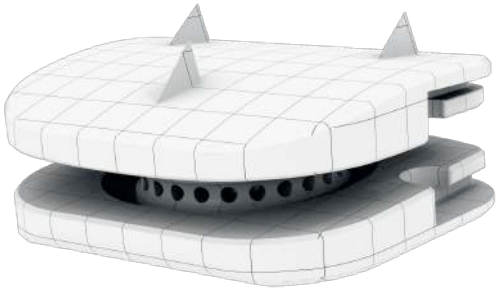
## STERILE INSTRUMENTS
## STERILE INSTRUMENTE

| | Art.No. / *Art.Nr.* | Description / *Beschreibung* | Q/M |
|---|---|---|---|
|  | A06 081 S | Z-Guide wire Ø 1,5, round / round, single use / *Z-Bohrdraht Ø 1,5, rund / rund, Einweg* | 2/5 |
|  | 900140 | First access needle 11G / *Zugangs-Nadel 11G* | 1/10 |
|  | 900146 | Bone cement filler cannula for cementation / *Bone cement filler cannula für Zementierung* | 1/10 |

Art. = Article number / Artikelnummer
Q = packaging unit / Packungseinheit
M = minimum order quantity / Mindestbestellmenge

# BAGUERA® C

**CERVICAL DISC PROSTHESIS**



## TWO-YEARS PROSPECTIVE CLINICAL FOLLOW-UP

**BY SPINEART**

# CERVICAL ARTHROPLASTY USING BAGUERA® C:
# OVERVIEW OF TWO-YEAR, PROSPECTIVE, CLINICAL FOLLOW-UP DATA REGISTRY

## POPULATION

118 patients were included in BAGUERA®C Registry, from 5 different hospitals in Europe, with two years prospective follow-up, through five follow-up visits, from 6 weeks to 2 years. The population studied includes 54 males (45.8%) and 64 females (54.2%), aged at the surgery time between 30 and 74 years. A total of 98 subjects were treated exclusively by TDR using BAGUERA®C, 70 subjects at 1 level, 25 subjects at 2 levels and 3 subjects at 3 levels. The rest of studied population, 20 subjects, underwent HYBRID surgery with 1 level TDR using BAGUERA®C for 14 subjects, 2 levels for 6 subjects. A total number of 149 BAGUERA®C cervical disc prostheses were implanted in 118 subjects at 4 cervical levels: C3-C4, C4-C5, C5-C6 and C6-C7.

## OVERALL SUCCESS EVALUATION

- No implant-related adverse events were recorded. No patient needed subsequent surgery. Three surgery-related adverse events were recorded.
- A clinical improvement of more than 20% of the NDI score after two years was observed in 81.8% of the TDR patients. In the HYBRID group, this improvement was observed in 50.0% of the patients.
- The neurological examination concerning reflexes, motor function and sensitivity revealed a stable or improved status in all patients in both groups.
- An improvement of more than 20% of the VAS score for neck pain was observed in 75.5% of the patients in the TDR-only group, and 55.0% of the patients in the hybrid group after two years. The minimum 20% improvement of the VAS score for arm pain was observed in 77.6% of the patients in the TDR-only group, and 70.0% of the patients in the hybrid group. All VAS Patient Satisfaction scores show more than 70% satisfaction, with a net positive trend after 3 months post-operative until the end of the observation period for TDR surgeries, with the best results for TDR 2 levels surgeries (91.11% satisfaction).
- A 15% or more improvement in quality of life as evaluated by the Short Form 36 questionnaire was recorded, respectively in 76.5% (TDR group) and 60.0% (HYBRID group) for the physical component of the questionnaire, and in respectively 77.6% (TDR group) and 50.0% (HYBRID group) for the mental health component of the questionnaire.

## CONCLUSION

Total disc replacement using BAGUERA®C device for the treatment of symptomatic cervical degenerative disc disease is a safe procedure with a low complication rate and in this study, no device-related adverse event. The best results were observed in patients of maximum 50 years of age, with no previous cervical or other spinal surgeries and with preoperative functional disabilities greater than 30% as evaluated by NDI.
TDR is an effective surgical treatment of one or two levels symptomatic cervical degenerative disc disease, whether used alone or in combination with other techniques. Functional improvement is slightly less frequent (30%) when HYBRID surgery is applied.

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http://dx.doi.org/10.4172/2165-7939.1000298

Research Article Open Access

# Radiographic Outcome and Adjacent Segment Evaluation Two Years after Cervical Disc Replacement with the Baguera®C Prosthesis as Treatment of Degenerative Cervical Disc Disease

**Patrick Fransen[1]*, Nils Hansen-Algenstaedt[2], Athanasios Chatzisotiriou[3], David Cesar Gonzalez Noriega[4], Jan Verheyden[5], Wim Van Hecke[5] and Vincent Pointillart[6]**

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## Abstract

**Introduction:** In many cases, cervical arthroplasty can avoid adjacent segment degeneration, by preserving the mobility of the operated level. In this paper, we present and analyze the radiological results of a cohort of patients who underwent cervical disc arthroplasty, with the Baguera®C cervical disc prosthesis.

**Material and methods:** 99 patients and a total of 123 prostheses were included in a retrospective analysis of radiographic images, based on a registry type data collection, with a two-year follow-up (FU). The radiological data was independently assessed for the range of motion, disc angle, disc height at the operated level and at the adjacent level, and for heterotopic ossifications (HO).

**Results:** At the operated level, the range of motion (ROM) decreased from 10.2° preoperatively to 8.7° (non-significant) after two years in the one level total disc replacement (TDR) group, from 9.8° to 9.1° (non-significant) in the two levels TDR group. The motion of the upper FSU changed from 10.6° preoperatively to 13.5° after two years in the one level TDR group, from 11.6° to 10.9° in the two levels group.

The disc height at the level of the operated FSU changed from 4 mm preoperatively to 7.1 mm after six weeks and 6.5 mm after two years for the one level TDR. The disc height at the level above the highest operated FSU changed from 4.24 mm preoperatively to 4 mm after six weeks and 4.2 mm after two years for the one level TDR, from 4.5 mm to 5.4 mm (6W) and 5.3 mm (2Y) for the two levels TDR.

No heterotopic ossification was observed in 46% of the patients. HO was observed, respectively 20.1% grade I, 14.5% grade II, 13.7% grade III and 5.6% grade IV. HO restricting mobility (grades III and IV) were seen in 19.3%. The prostheses were mobile in 80.6% after two years.

**Conclusion:** Cervical arthroplasty using the Baguera®C prosthesis, demonstrated cervical mobility preservation in 80.6% of the patients, an HO rate of 54%, mostly grade I and II, no signs of subsidence and no signs of degeneration or kyphosis of the adjacent disc. This motion preserving surgical treatment, either used alone or in combination with segmental fusion, shows encouraging results in term of adjacent level disease protection and appears, therefore, as safe and effective.

**Keywords:** Cervical disc; Ossification; Spondylarthrosis; Vertebrae

**Abbreviations**: TDR - Total Disc Replacement; ROM - Range Of Motion; FSU- Functional Spinal Unit; Ns: Non-Significant (Statistically); HO - Heterotopic Ossifications; FU - Follow-Up; COV - Coefficient Of Variation; SD - Standard Deviation; ICC - Intraclass Correlation Coefficient; PO - Post-Operative; SCDD - Symptomatic Cervical Disc Disease; PE - Polyethylene; DLC - Diamond-Like Carbon; AP - Antero-Posterior; ANOVA - Analysis of Variance

## Introduction

Anterior cervical discectomy and fusion has been first introduced by Cloward and by Smith and Robinson [1,2] in 1958 and 1963 respectively. Although the clinical results were and still are excellent, the conversion of a functionally mobile spinal unit into an intersomatic fusion has disadvantages. The rigidity of a single fused segment is often well tolerated, but may cause increased strain at the levels i immediately adjacent to the fused segment [3].

Radiological changes have been described mainly above fused cervical discs. Cervical arthroplasty with artificial discs has been used for more than 10 years now, with clinical results equivalent or slightly superior to fusion in selected cases [4,5]. Theoretically, cervical arthroplasty could, by preserving the mobility of the operated level, avoid adjacent segment degeneration.

We describe the radiological results of a cohort of patients who underwent cervical disc arthroplasty, with single or double levels Baguera®C cervical disc prostheses.

## Material and Methods

Based on a registry type data collection, we present a retrospective

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analysis of radiographic images. This allows for a quantitative assessment of the treatment's results, two years after implantation of the Baguera®C Prosthesis.

The registry contains data referring to subjects who underwent one- or multilevel arthroplasty using the Baguera®C prosthesis alone or in combination with other surgical treatments (i.e. arthrodesis, referred to as hybrid constructs), and were followed postoperatively for two years. All preoperative, intraoperative and postoperative follow-up visits were documented clinically and radiographically.

## Primary and secondary objectives

Two primary objectives were defined: (i) motion at the treated level two years after total disc replacement (TDR), evaluated by its range of motion (ROM) between flexion and extension (motion being defined by a ROM of at least 2°), and (ii) disc height restoration two years after TDR.

The four secondary objectives were defined as: (i) motion at the adjacent level two years after TDR, evaluated by its ROM between flexion and extension (motion being defined by a ROM of at least 2°), (ii) overall cervical alignment, evaluated as overall lordosis by measuring C2-C7 angle, (iii) balance of the spine, evaluated by the angle of functional spine unit (FSU) at the treated level and (iv) impact on adjacent levels, evaluated by the upper adjacent angle and the upper disc height.

## Demographics

99 patients from five European investigation centers were included in the analysis. X-Ray images used for the radiographic assessment were collected during three visits: Pre-operative visit, 6 weeks follow-up and 2 years follow-up.

60 patients had one-level surgery, 30 patients had two-level surgery and 9 patients had three-level surgery. 18 patients were treated with hybrid constructs (12 operated at two-levels – one prosthesis, one fusion - and 6 operated at three-levels –one prosthesis, two fusions). 81 patients were treated by prosthesis implantation only (60 operated at one-level, 18 operated at two-levels and 3 operated at three levels).

A total of 123 prostheses were utilized: 4 prosthesis were implanted in C3-C4, 19 in C4-C5, 53 in C5-C6 and 47 in C6-C7.

## Inclusion and exclusion criteria

To be included in the registry, the patients had to suffer from symptomatic cervical disc disease (SCDD) between C3 and C7, as defined by the following signs and symptoms: neck or arm pain and/or functional and/or neurological deficit caused by herniated nucleus pulposus and/or spondylarthrosis defined by the presence of osteophytes and/or disc height reduction as confirmed by MRI or X-ray. We included patients aged between 18 and 75 years, not responding to non-surgical treatment for a period of at least six weeks, or presenting signs of progressive nerve root compression despite conservative treatment. Finally, included patients had to be psychologically, physically and mentally able to comply with the treatment protocol.

Exclusion criteria were: severe injury or degeneration of the facet joints confirmed by X-ray, known allergy to any of the constituent materials, prior cervical fractures, severe spondylarthrosis at the treatment site (syndesmophytes and/or absence of mobility (ROM < 2°)), pain unrelated to the cervical disc disease, metabolic bone disease (osteoporosis), Paget disease, severe diabetes requiring daily insulin treatment, pregnancy, active infection (systemic or local), rheumatoid arthritis or other auto-immune disease, systemic disease, including AIDS/HIV and hepatitis or active malignancy.


**Figure 1:** Baguera®C prosthesis.

All included patients accepted to sign an informed consent form. The registry protocol was reviewed by the local ethics committee on each site. The radiological assessment was performed in a semi-automatic way by an independent evaluator (icoMetrix NV, Leuven, Belgium).

## Implant characteristics

The Baguera®C cervical prosthesis (Spineart SA, Geneva, Switzerland) is a biomechanical device designed to be used for TDR. It consists of a high-density polyethylene (PE) nucleus that articulates between two titanium endplate components, with a porous-titanium-coated exterior and a bioceramic (DLC)-coated-interior, in contact with the PE nucleus (Figure 1). The primary stability is obtained by the convex shape of the superior endplate and by three fins on each endplates that allow safe anchoring of the prosthesis i mmediately after the release of the Caspar retractor used during the discectomy. The secondary stability is obtained by bone growth inside the porous titanium coating. The implant allows a physiological rotation as well as translation in both the antero-posterior (AP) (± 0.3 mm) and rotational (± 2°) directions. The controlled mobility of the PE nucleus is designed to prevent excessive constraints on the facet joints, and its rolling feature respects axial rotation movements. The concave superior aspect of the inferior plate and PE nucleus shape allow 0.15 mm elastic deformation to absorb shocks and vibrations

## Radiological evaluation protocol

Radiographic images preoperatively, at 6 weeks follow-up and at 2 years follow-up were evaluated for 10 parameters in neutral, flexion and extension position, related to the following three measurements: range of motion (ROM), angles and height.

A semi-automatic process was setup and performed by icoMetrix NV. The manual part, the Annotations phase, used a graphical user interface specially developed for marking and capturing coordinates related to implant and cervical vertebrae. Four landmarks corresponding to the corners were used for vertebrae identification, and they were marked by an expert radiologist using mouse clicks (Figures 2a-2c). Coordinates were automatically recorded in a structured .xml format and used by the automatic component developed using Python (http://www.python.org) as input for all calculations.

Errors of measurement (coming from both manual and algorithmic components) were estimated for each parameter by an extensive reproducibility study: The absolute error, the relative error and the reproducibility coefficients were taken as the standard deviation (SD), the coefficient of variation (CoV) and the intra-class correlation (ICC) respectively. An ANOVA, two-way effect model, was used to quantify the absolute agreement.

The ROM (in degrees) describes the mobility of the observed spine unit. The angles that are used to transform the vertebrae above and below the Baguera®C between flexion and extension provide the range of motion (Figure 3). It was assessed using the flexion and extension images by using a registration (image alignment) algorithm,

which aims at matching two vertebrae in the flexion image with the corresponding vertebrae in the extension image. As a result, two transformations are obtained that describe the matching of the first vertebrae between flexion and extension and the second vertebrae between flexion and extension. Based on the difference between these two geometrical transformations, the range of motion was calculated. The same automatic procedure was used to evaluate the range of motion at the treated level, upper adjacent level, overall between C2 and C7 and overall between C2 and C6.

The disc angle (in degrees) is the angle between the plates of adjacent levels and represents the balance of the spine. It was assessed using neutral images after determination of four landmark points. These landmarks were positioned on the inferior corners of the vertebral body below the artificial disc and on the superior corners of the vertebra above the artificial disc. Once these points were in place, lines connecting the landmarks were automatically drawn (Figure 4). As a result, the angle between both endplates was calculated. The same semi-automated procedure was used to measure the angle of the FSU at the treated level, upper adjacent FSU, and the angle of the overall spine between C2-C7 and C2-C6. The FSU (functional spinal unit) is

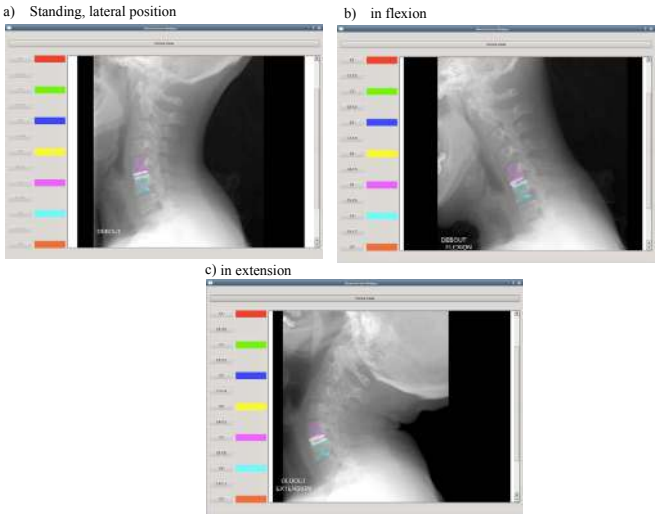



**Figure 2:** Radiographic images two years after surgery (annotated) Subjects who underwent 1 level (C5-C6) total disc replacement using Baguera®C.

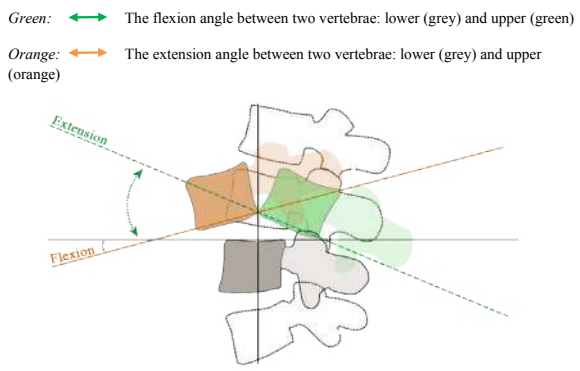



**Figure 3:** Range of Motion (ROM): The angles used to transform the vertebrae above and below the Baguera®C between flexion and extension provide the range of motion. Grey color is used for lower vertebra. Green and orange are used for upper vertebra in extension and flexion, respectively. The fixed reference for flexion and extension angles, corresponding to the superior plate of lower vertebra, is the black (horizontal) line.

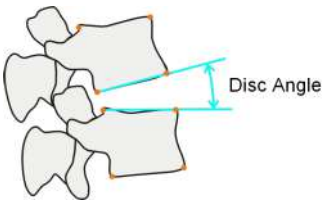



**Figure 4:** Disc angle.

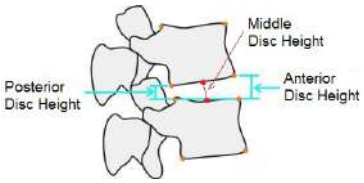



**Figure 5:** Disc height (middle).

the entity regrouping a disc, the two corresponding facet joints and the two adjacent vertebrae.

Disc height is the distance (in millimeters) between the upper plate of the lower vertebra and the lower plate of the upper vertebra: We used, as its measure, the middle disc height, i.e. the distance measured perpendicular to the plane of the top plate at mean distance (Figure 5). This distance is used to assess the disc height restoration. The disc height was assessed using neutral images, after calibration to cancel any magnification factor.

Heterotopic ossifications (HO) were addressed and classified according to the McAfee classification modified by Mehren et al. [6] The classification has a 5-points grading system: grade 0 = no HO; grade I = presence of HO but not in the interdiscal space; grade II = presence of HO in the interdiscal space; grade III = bridging of ossification with segment movement; grade IV = complete fusion without movement in flexion/extension.

## Statistical analysis

The statistical analysis was performed using SAS®9.3 and results are presented as su mmary statistics, overall and by type of surgery, study visit, treated level, illustrated by tables and figures.

Comparisons between preoperative and postoperative values were performed and statistical significance of observed change in values was noted. The results with $p<0.05$ were considered significant. Only subjects with available data at all 3 visits (preoperative and postoperative at 6 weeks, 2 years respectively) were included in these comparisons.

Parametric (paired t-test) or non-parametric Wilcoxon (signed-rank) test was used depending on normality. The normality of distributions was evaluated by Shapiro-Wilcoxon (sign-rank) test.

Comparisons between preoperative and postoperative values were made using paired t-test for normal distributed data and Wilcoxon test when normality was not confirmed.

# Results

## Range of motion of the functional spine unit

At the operated level, the ROM decreased from 10.2 ° (preoperatively) to 8.7° (ns) after two years in the one level TDR, from 9.8° to 9.1° (ns) in two levels TDR. The decrease was more pronounced in the three levels TDR, dropping from 13.2° preoperatively to 5.9° (ns) after two years, but on a smaller cohort of patients (Table 1). Figure 6

illustrates all results for subjects who underwent one-level TDR, at pre-operative and postoperative visits (left) and by treated level at 2-year FU (right).

For the hybrid constructs, the ROM of the prostheses decreased from 10.7° to 6.9° after two years when implanted in association with one level fusion, and from 11.66° to 7.7° when implanted in association with two fused levels.

## Range of motion of the upper functional spine unit

The motion of the upper FSU changed from 10.6° preoperatively to 13.5° after two years in the one level TDR group, from 11.6° to 10.9° in the two levels group and from 11.1° to 7.1° in the three levels group (Table 2). Figure 7 illustrates all results for subjects who underwent one-level TDR, at pre-operative and postoperative visits (left) and by treated level at 2-year FU (right).

## Range of motion of the C2C7 levels and C2C6 levels

The overall range of motion of the C2C7 levels changed from 51.1° to 54° after two years in the one level TDR group, from 50.2° to 46.8° in the two levels group and from 60.7° to 32.3° in the three levels group (Table 3). Figure 8 illustrates all results for subjects who underwent one-level TDR, at pre-operative and postoperative visits (left) and by treated level at 2-year FU (right).

Not surprisingly, in the hybrid group the overall C2C7 ROM decreased according to the number of fused levels, changing from 48.2° preoperatively to 40.8° when the prosthesis was implanted in association with one level fusion, and from 75.2° to 28.5° when the prosthesis was implanted in association with two fused levels.

Similar tendencies were observed when measuring the C2C6 ROM.

## Angle of the functional spine unit

At the operated level, the angle changed from 5.6° preoperatively to 6.3° after two years for the one level TDR, from 4.6° to 6.8° for the two-level TDR and from 8.21° to 3.93° for the three-levels TDR.

## Angle of the upper functional spine unit

The angle of the level above the operated level changed from 7.4° preoperatively to 6.4° after two years for the one level TDR, from 6.8° to 7.6° for the two-level TDR and from 10.8° to 5.2° for the three-levels TDR.

## Overall angle of the C2C7 levels and of the C2C6 levels

The overall C2C7 angle changed from 19.9° preoperatively to 12.8° after two years for the one level TDR, from 27.5° to 16.8° for the two-level TDR and from 20.7° to 13.2° for the three-levels TDR.

The overall C2C6 angle changed from 19.17° preoperatively to

| Type of Surgery | BAGUERA®C implanted | Treated Levels | Pre-op | | 6W (PO) | | 2Y (PO) | | Pre-op vs 2Y (absolute change) | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | Mean | SD | Mean | SD | Mean | SD | Mean | p-value |
| TDR | 1 | 1 | 10.25 | 4.1 | 8.55 | 4.4 | 8.79 | 4.6 | -1.3 | ns |
| | 2 | 2 | 9.80 | 4.7 | 6.90 | 3.4 | 9.15 | 5.3 | -0.04 | ns |
| | 3 | 3 | 13.26 | 3.3 | 7.21 | 3.3 | 5.99 | 3.5 | -6.43 | ns |
| HYBRID | 1 | 2 | 10.70 | 3.9 | 5.65 | 3.8 | 6.99 | 4.0 | -4.72 | 0.05(*) |
| | | 3 | 11.66 | 3.2 | 7.59 | 3.0 | 7.75 | 0.4 | - | - |
| (*) - p-value from Wilcoxon teste. | | | | | | | | | | |

**Table 1:** Range of Motion at the treated level (ROM-FSU) (degrees): Pre-operative vs. post-operative values. Summary statistics: Overall and by number of treated levels.

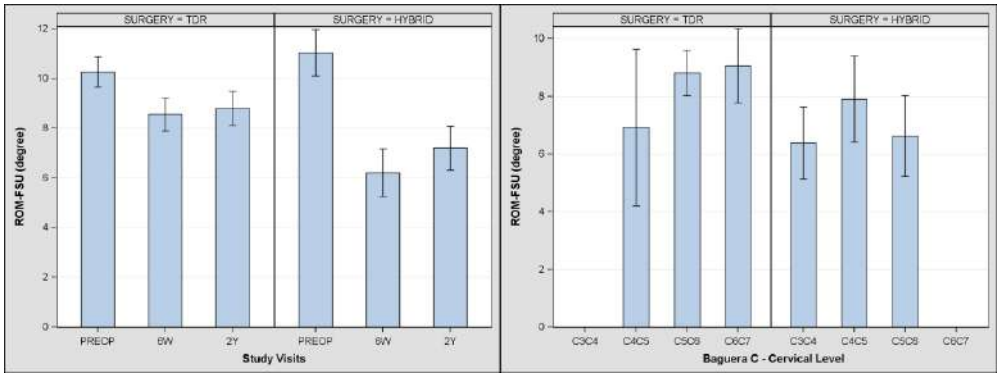



**Figure 6:** Range of Motion at the treated level (ROM-FSU). **Left:** Pre- and post-operative values for subjects treated by 1 level TDR using Baguera®C. Non-significant changes between pre-operative and post-operative data were observed. **Right:** Two years after surgery values, by treated level for subjects who underwent 1 level TDR using Baguera®C, by type of surgery (TDR, HYBRID).

| Type of Surgery | BAGUERA®C implanted | Treated Levels | Pre-op | | 6W (PO) | | 2Y (PO) | | Pre-op vs 2Y (absolute change) | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | Mean | SD | Mean | Mean | Mean | SD | Mean | p-value |
| TDR | 1 | 1 | 10.64 | 5.2 | 10.91 | 5.0 | 13.54 | 5.4 | 2.79 | ns |
| | 2 | 2 | 11.66 | 4.7 | 7.86 | 3.6 | 10.94 | 5.1 | -0.64 | ns |
| | 3 | 3 | 11.15 | 4.3 | 6.50 | 4.0 | 7.19 | 3.7 | -3.78 | ns |
| HYBRID | 1 | 2 | 10.36 | 6.1 | 6.57 | 5.3 | 9.99 | 6.5 | 0.08 | ns |
| | | 3 | 11.04 | 4.9 | 8.15 | 5.4 | 10.30 | 2.9 | -2.86 | ns |

**Table 2:** Range of Motion at the upper adjacent level (UPPER ROM): Preoperative vs. postoperative values. Summary statistics: Overall and by number of treated levels.

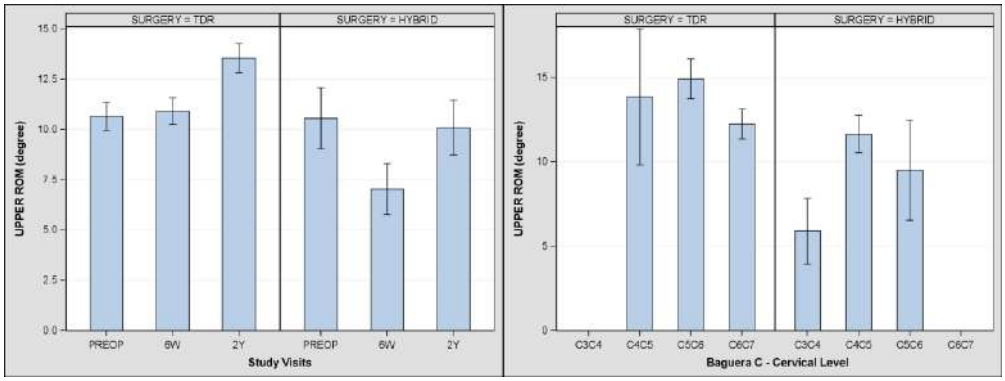



**Figure 7:** Range of Motion at the upper adjacent level (UPPER ROM). **Left:** Pre- and post-operative values for subjects treated by 1 level TDR using Baguera®C. Significant improvement (p=0.01) between pre-operative and 2 year's post-operative data. **Right:** Two years after surgery values, by treated level for subjects who underwent 1 level TDR using Baguera®C, by type of surgery (TDR, HYBRID).

| Overall cervical ROM | Type of Surgery | BAGUERA®C implanted | Treated Levels | Pre-op | | 6W (PO) | | 2Y (PO) | | Comparison: Pre-op vs 2Y | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | Mean | SD | Mean | SD | Mean | SD | Mean | p-value |
| C2-C7 | TDR | 1 | 1 | 51.50 | 15.0 | 43.93 | 15.4 | 54.03 | 11.6 | 5.32 | ns |
| | | 2 | 2 | 50.20 | 13.7 | 37.82 | 15.4 | 46.88 | 8.9 | -0.02 | ns |
| | | 3 | 3 | 60.74 | 6.8 | 33.84 | 8.5 | 32.38 | 13.1 | - | - |
| | HYBRID | 1 | 2 | 48.20 | 21.1 | 42.34 | 5.4 | 40.86 | 14.1 | - | - |
| | | | 3 | 75.20 | . | 18.41 | 9.0 | 28.58 | 7.5 | - | - |
| C2-C6 | TDR | 1 | 1 | 42.07 | 12.4 | 38.98 | 11.2 | 47.10 | 11.0 | 4.43 | ns |
| | | 2 | 2 | 43.02 | 11.9 | 31.11 | 10.9 | 41.72 | 10.6 | -1.13 | ns |
| | | 3 | 3 | 44.53 | 0.8 | 28.40 | 7.2 | 28.62 | 7.0 | -15.91 | ns |
| | HYBRID | 1 | 2 | 40.91 | 15.5 | 26.33 | 14.9 | 31.94 | 10.3 | -6.47 | ns |
| | | | 3 | 38.46 | 9.3 | 18.39 | 12.5 | 29.53 | 9.7 | -12.29 | ns |

**Table 3:** Overall cervical range of motion (ROM-C2C7 and ROM-C2C6) (degrees): Preoperative vs. postoperative values. Summary statistics: Overall and by number of treated levels.

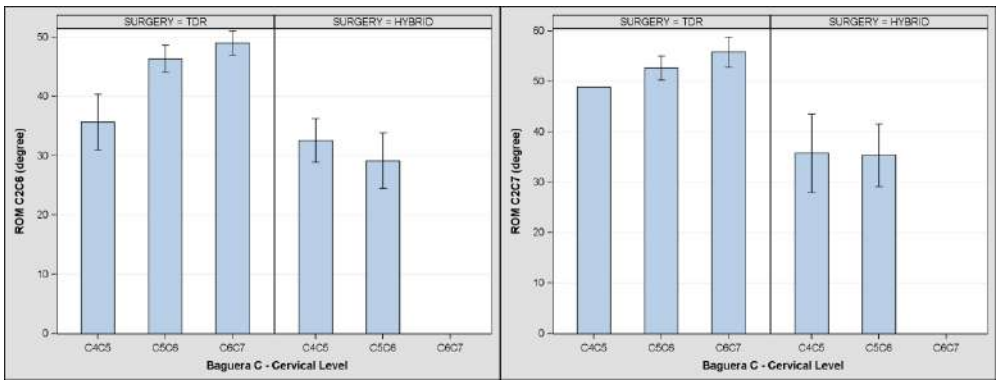



**Figure 8:** Overall cervical range of motion two years after surgery for subjects who underwent 1 level TDR using Baguera®C by treated level and type of surgery (TDR, HYBRID): ROM-C2C6 (left), ROM-C2C7 (right).

10.4° after two years for the one level TDR, from 24.7° to 15.8° for the two-level TDR and from 14.7° to 13.7° for the three-levels TDR

## Disc height of the functional spine unit

The disc height at the level of the operated FSU changed from 4 mm preoperatively to 7.1 mm after six weeks and 6.5 mm after two years for the one level TDR, from 4. mm to 7.5 mm (6W) and 6.5 mm (2Y) for the two levels TDR and 5.1 mm to 7.6 mm (6W) and 7.3 mm (2Y) for the three-levels TDR.

## Disc height of the upper functional spine unit

The disc height at the level above the highest operated FSU changed from 4.2 mm preoperatively to 4 mm after six weeks and 4.2 mm after two years for the one level TDR, from 4.5 mm to 5.4 mm (6W) and 5.3 mm (2Y) for the two levels TDR and 5.5 mm to 6.4 mm (6W) and 6.2 mm (2Y) in the three levels TDR.

## Heterotopic ossifications

Heterotopic ossifications were measured at the operated level in all 99 patients, accounting for a total of 123 operated levels.

No HO was observed in 46% of the patients (grade 0).

The HO grade for the remaining 54% was: grade I (for 20.1%), grade II (for 14.5%), grade III (for 13.7%) and grade IV (for 5.6%).

HO restricting mobility (grades III and IV) were observed in 19.3% of the patients.

The prostheses were thus mobile in 80.6% of the patients after two years.

## Discussion

Although this series covers a limited number of patients, and presents with limitations inherent to its retrospective nature, we found out that most published studies present the same structure and that therefore, a comparison with the literature data was reasonable.

### Relevance of the measure

In order to ensure the clinical usability of these results, the relatively scarce, existing, literature was thoroughly reviewed. This provided the necessary insight on which measurements to perform, to evaluate spine mobility and balance [7-12], and on the values to expect: e.g. the ROMs as reported in Sasso et al. [9] or Bertagnoli et al. [8]. Based on these studies, we expected average ROMs to vary between 5° and 15°. Therefore, we aimed at achieving a standard error on the ROM measurement of around 1°, in order to be able to capture the differences between pre-op, 6 weeks and 2 years images. Thanks to the automated measure method, we achieved a sufficient precision in both angular and distance measurements.

### Mobility at the operated level

Mobility at the treated level after two years of total disc replacement (TDR) using Baguera®C was evaluated by the range of motion (ROM) between flexion and extension; mobility is present when ROM value is at least 2°, or better 4° as suggested by J.Vital et al. [13,14].

The fact that motion slightly decreased after two years is not an issue because this diminish the constraint on facet joint that can be painful.

Two years after surgery, mobility at the operated level for patients treated by only TDR using Baguera®C was noted for 93%, 93.6% and 87.5% of treated levels, when one-level, two-levels and three-level TDR respectively was performed. In case of Hybrid treatment, mobility at the treated levels was observed for 81.8% and 100% of treated levels when one-level TDR was associated with one or respectively two-level arthrodesis. We observed better results for 1-level TDR (8.79°,) compared to results reported by Sasso et al. [5] and [9] reporting 8.79° and 6.7°, respectively), and Ryu et al. [15] reporting 7.9° for Bryan group and 4.1° for Prodisc group), the average values after 2 years post-surgery.

One explanation for these good results is that semi-constrained prostheses featuring a semi mobile nucleus could enable a more physiological movement than constrained prosthesis with a fixed center of rotation that could limit movement of the operated segment and cause painful friction of the facet joints.

### Disc height at the operated level

The disc height was increased after TDR, changing from an average 4.44 mm (1level), 4.35 mm (2 levels) and 4.92 mm (3 levels) preoperatively to respectively 7.27 mm, 6.87 mm and 7.72 mm after two years. The increased disc height was constant between the 6W observation and the 2Y observation, showing no signs of subsidence.

Our data show better results in terms of disc height restoration after 2 years, (6.5 mm in average for 1 level TDR, 6.54 mm for 2 levels TDR), compared to published data by Ryu et al. [15], reporting at the last FU in average 3.3 mm for Bryan group and 3.5 mm for Prodisc group.

### Adjacent level degeneration

Although the assessment of adjacent level degeneration over a two years period is debatable, we tried to monitor the changes of the FSU cranial to the highest TDR level, assuming that potential changes would reflect increased stress and more chances of further degeneration.

In the one-level patients, we observed a slightly increased ROM from 10.46° to 13.57°. This increase was not observed in the two- and three levels patients who showed a decreased ROM from 11.66° to 10.94° and from 11.15° to 7.19°, respectively in the two and three levels group.

Also, the measure of the adjacent FSU angle showed no significant sagittal balance changes and the adjacent FSU disc height was preserved. Our interpretation of this data is that TDR had little or no influence on the evolution of the adjacent level over the two years observation period.

### Heterotopic ossifications

Several authors have studied heterotopic ossifications with various disc prosthesis [6,14-17]. In some studies, a high rate of HO occurrence and a limitation of mobility were observed: Suchomel et al. [17] studied 65 Prodisc C prostheses. HO was present in 86% of the patients after two years. During a 48-month period on the same cohort, they also found that significant HO (grade III) was present in 45% of the implants and that segmental ankylosis (grade IV) was present in another 18%, adding up to a total of 63% of non-mobile prosthesis. Also, Lee reported 77% HO in a group of patients treated with the Mobi C prosthesis, with two years FU [16], and Mehren reported 66.2% of HO only one year after cervical disc replacement with the Prodisc C prosthesis [6].

Other studies, however, report less concerning results: Tu et al. [14] reported a 50% general rate of HO with the Bryan prosthesis, with less than two years FU. Similarly Ryu et al. [15] reported 57% HO for the Bryan prosthesis and 47% HO for the Prodisc C on a small group of patients and with two years FU.

Our study scores show better results, with an overall HO grade of 54%, mostly grade I and II, explaining the rather high 80.64% rate of mobile implants after two years. We attribute these good results to the semi constrained and more physiological design of the prosthesis and to the careful selection criteria.

Finally, the fact that data from different cervical levels have been combined, may potentially influence the final results of this analysis and should therefore is considered as a limitation of this study.

## Conclusion

Radiographic data coming from subjects enrolled in the Baguera®C Registry who met inclusion criteria for current analysis, demonstrate cervical mobility preservation in 80.64% of the patients, and an HO rate of 54%, mostly grade I and II.

There were no signs of subsidence of the prostheses. Measures at the level adjacent to the TDR showed no signs of degeneration, no signs of kyphosis and the adjacent disc height was preserved.

Cervical arthroplasty using the Baguera®C prosthesis is thus a safe, effective and motion preserving surgical treatment, either used alone or in combination with segmental fusion, showing encouraging results in term of adjacent level disease protection.

### References

1. Smith GW, Robinson RA (1958) The treatment of certain cervical-spine disorders by anterior removal of the intervertebral disc and interbody fusion. J Bone Joint Surg Am 40A: 607-624.

2. Cloward RB (1963) Lesions of the intervertebral disks and their treatment by interbody fusion methods. The painful disk. Clin Orthop Relat Res 27: 51-77.
3. Hilibrand AS, Carlson GD, Palumbo MA, Jones PK, Bohlman HH (1999) Radiculopathy and myelopathy at segments adjacent to the site of a previous anterior cervical arthrodesis. J Bone Joint Surg Am 81: 519-528.
4. Phillips FM, Lee JYB, Geisler FH, Cappuccino A, Chaput CD, et al. (2013) A prospective, randomized, controlled clinical investigation comparing PCM cervical disc arthroplasty with anterior cervical discectomy and fusion. Spine 38: E907–E918.
5. Sasso RC, Anderson PA, Riew KD, Heller JG (2011) Results of cervical arthroplasty compared with anterior discectomy and fusion: four-year clinical outcomes in a prospective, randomized controlled trial. J Bone Joint Surg 93: 1684–1692.
6. Mehren C, Suchomel P, Grochulla F, Barsa P, Sourkova P, et al. (2006) Heterotopic ossification in total cervical artificial disc replacement. Spine (Phila Pa 1976) 31: 2802-2806.
7. Wigfield C, Gill S, Nelson R, Langdon I, Metcalf N, et al. (2002) Influence of an artificial cervical joint compared with fusion on adjacent-level motion in the treatment of degenerative cervical disc disease. J Neurosurg 96: 17–21.
8. Bertagnoli R, Yue JJ, Pfeiffer F, Fenk-Mayer A, Lawrence JP, et al. (2005) Early results after ProDisc-C cervical disc replacement. J Neurosurg Spine 2: 403-410.
9. Sasso RC, Best NM (2007) Cervical kinematics after fusion and bryan disc arthroplasty. J Spinal Disord 21: 19-22.
10. Nabhan A, Ishak B, Steudel WI, Ramadhan S, Steimer O (2011). Assessment of adjacent-segment mobility after cervical disc replacement versus fusion: RCT with 1 year's results. Eur Spine J 20: 934-941.
11. Mummaneni PV, Burkus JK, Haid RW, Trainelis VC, Zdeblick TA (2007). Clinical and radiographic analysis of cervical disc arthroplasty compared with allograft fusion: a randomized controlled clinical trial. J Neurosurg Spine 6: 198-209.
12. Zechmeister I, Winkler R, Mad P (2011). Artificial total disc replacement versus fusion for the cervical spine: a systematic review. Eur Spine J 20: 177-184.
13. Vital JM, Guérin P, Gille O, Pointillart V (2011) Prothèses discales cervicales. EMC: 44-162.
14. Tu TH, Wu JC, Huang WC, Guo WY, Wu CL, et al. (2011) Heterotopic ossification after cervical total disc replacement: determination by CT and effects on clinical outcomes. J Neurosurg Spine 14: 457-465.
15. Ryu KS, Park CK, Jun SC, Huh HY (2010) Radiological changes of the operated and adjacent segments following cervical arthroplasty after a minimum 24-month follow-up: comparison between the Bryan and Prodisc-C devices. J Neurosurg Spine 13: 299-307.
16. Lee SE, Chung CK, Jahng TA (2012) Early development and progression of heterotopic ossification in cervical total disc replacement. J Neurosurg Spine 16: 31-36.
17. Suchomel P, Jurák L, Benes V, Brabec R, Bradác O, et al. (2010) Clinical results and development of heterotopic ossification in total cervical disc replacement during a 4-year follow-up. Eur Spine J 19: 307-315.

**Citation:** Fransen P, Hansen-Algenstaedt N, Chatzisotiriou A, Noriega DCG, Verheyden J, et al. (2016) Radiographic Outcome and Adjacent Segment Evaluation Two Years after Cervical Disc Replacement with the Baguera®C Prosthesis as Treatment of Degenerative Cervical Disc Disease. J Spine 5: 298. doi:10.4172/2165-7939.1000298

# BAGUERA®C Study #16001

## Cervical Arthroplasty using BAGUERA® C: A two-year, prospective, clinical follow-up data registry. Retrospective clinical analysis results

***Not FDA approved. Non-US study***
***Region: Europe***
***Status: Completed***

***Pilot study for registration in various countries***

**Primary Objectives:**

- **Safety Evaluation:**
  Evaluation at the end of 2 years post-operative follow-up of the safety of the BAGUERA®C cervical disc prosthesis by analyzing all adverse events reported during the observation period, whether anticipated or unanticipated, related or not to the use of the device.

- **Effectiveness Evaluation:**
  An **overall success rate** was defined as a composite primary endpoint, based on individual overall success evaluated for each subject at 24 months post-operative, based on five parameters taken from clinical and safety evaluation:
  1. *Functional improvement* of 20% at 24 months post-operative, compared to the pre-operative status, evaluated by the Neck Disability Index (NDI).
  2. *Neurological improvement*: conservation of or improvement in three main components of the neurological status: *motor functions, reflexes, sensibility*.
  3. *Neck and Arm Pain*: pain relief of 20% at 24 months post-operative, compared to the pre-operative status, evaluated by VAS scores.
  4. *Improvement in Health-related Quality of Life* of 15% at 24 months post-operative, compared to the pre-operative status, assessed using the Short-Form-36 questionnaire (SF-36 scores)
  5. *No subsequent surgery*.

**Indication - condition:** Symptomatic cervical degenerative disc disease one or two levels from C3 to C7

**Study type:** Observational, prospective data collection (registry), retrospective analysis, multicenter cohort study

**Patients enrolled:** 118

**Primary outcomes:**

- NDI scores
- Adverse events:
  - Duration (starts and end dates),
  - Seriousness, Intensity, Severity, Anticipated/Unanticipated
  - Relationship to the implant (suspected/not suspected),
  - Re-interventions, Revisions,
  - Relationship to the surgery (suspected/not suspected),
  - Removals or supplemental fixation.
- Neck and Arm Pain by Visual Analogic Scale (VAS)
- Neurological status: motor functions, reflexes, sensibility
- SF-36 scores

# BAGUERA®C Study #16002

## Cervical Arthroplasty using BAGUERA® C: A two-year, prospective, clinical follow-up data registry. Retrospective radiographic evaluation

***Not FDA approved. Non-US study***
***Region: Europe***
***Status: Completed***

***Pilot study for registration in various countries***

**Primary Objectives:**

1. *Motion* at the treated level after two years of total disc replacement (TDR) using Baguera C prosthesis, evaluated by its range of motion (ROM) between flexion and extension; motion occurs when ROM value is at least 2°;
2. *Disc height restoration* after two years of total disc replacement (TDR) using Baguera C prosthesis.

**Secondary Objectives:**

1. *Motion* at the adjacent level after two years of total disc replacement (TDR) using Baguera C prosthesis, evaluated by its range of motion (ROM) between flexion and extension; motion occurs when ROM value is at least 2°;
2. *Overall cervical alignment,* evaluated as overall lordosis by measuring C2-C7 ROM;
3. *Balance of the spine*, evaluated by the angle of functional spine unit (FSU) at the treated level;
4. *Impact on adjacent levels,* evaluated by the upper adjacent angle and the upper disc height.

**Indication - condition:** Symptomatic cervical degenerative disc disease one or two levels from C3 to C7

**Study type:** Observational, prospective data collection (registry), retrospective analysis, multicenter cohort study

**Patients enrolled:** 96

**Primary outcomes:**

- ROM FSU : Range of motion (ROM) of the Functional Spine Unit (FSU)
- HEIGHT: Disc Height

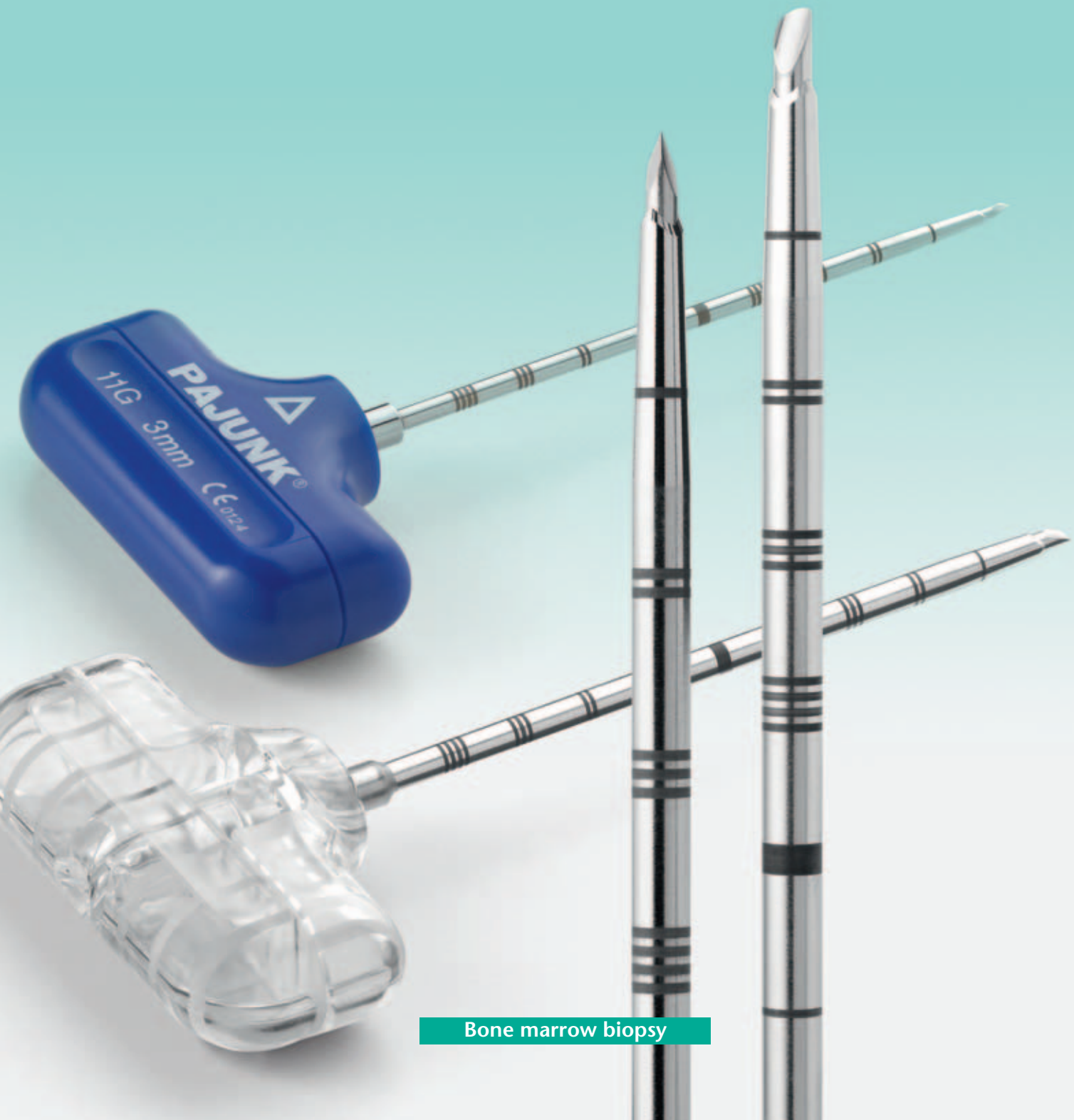
**Secondary outcomes:**

- UPPER ROM: Range of motion of the Upper Functional Spine Unit
- ROM C2-C6: Range of motion of C2-C6 levels
- ROM C2-C7: Range of motion of C2-C7 levels
- ANGLE FSU: Angle of the Functional Spine Unit
- UPPER ANGLE: Angle of the Upper Functional Spine Unit
- ANGLE C2-C6: Angle of C2-C6 levels
- ANGLE C2-C7: Angle of C2-C7 levels
- UPPER HEIGHT: Disc Height of the Upper Functional Spine Unit

PAJUNK®

# *TrokaBone / TrokaCut*

*Aspiration and puncture cannulas for bone marrow biopsy*




**Bone marrow biopsy**

## *TrokaCut and TrokaBone*

# *Cannula systems for bone marrow biopsy*

*The manufacture of cannula systems for biopsy has been the core competence of PAJUNK® for more than 45 years. Together with doctors from different fields, PAJUNK® develops sophisticated solutions for bone marrow biopsy, fine-needle biopsy, cutting and punch biopsy, brachytherapy and tumour markers. PAJUNK® offers three systems in the field of bone marrow biopsy: TrokaCut, TrokaBone and TrokaBone Sternal. They differ with respect to material usage, design and the field of application.*

**Tip with bevelled hollow grind**

## *TrokaCut*

*the combined aspiration and punch cannula for pelvic crust puncture*



The semi-transparent plastic bayonet lock of **TrokaCut** allows the outer cannula and full stylet to be permanently connected to each other.


A stable metal anchoring system is used to fasten the outer cannula in the handle for **TrokaBone**. This complete system is manufactured from robust materials and is characterised by its excellent stability and the ergonomic handle.

## *TrokaBone*

*the combined aspiration and punch cannula for pelvic crest puncture*




**Tip with bevelled hollow grind**

**Tip with trocar grind**

## *TrokaBone Sternal*

*the puncture set for safe aspiration of bone marrow from the pelvic and sternum region*


**Tip with bevelled grind**

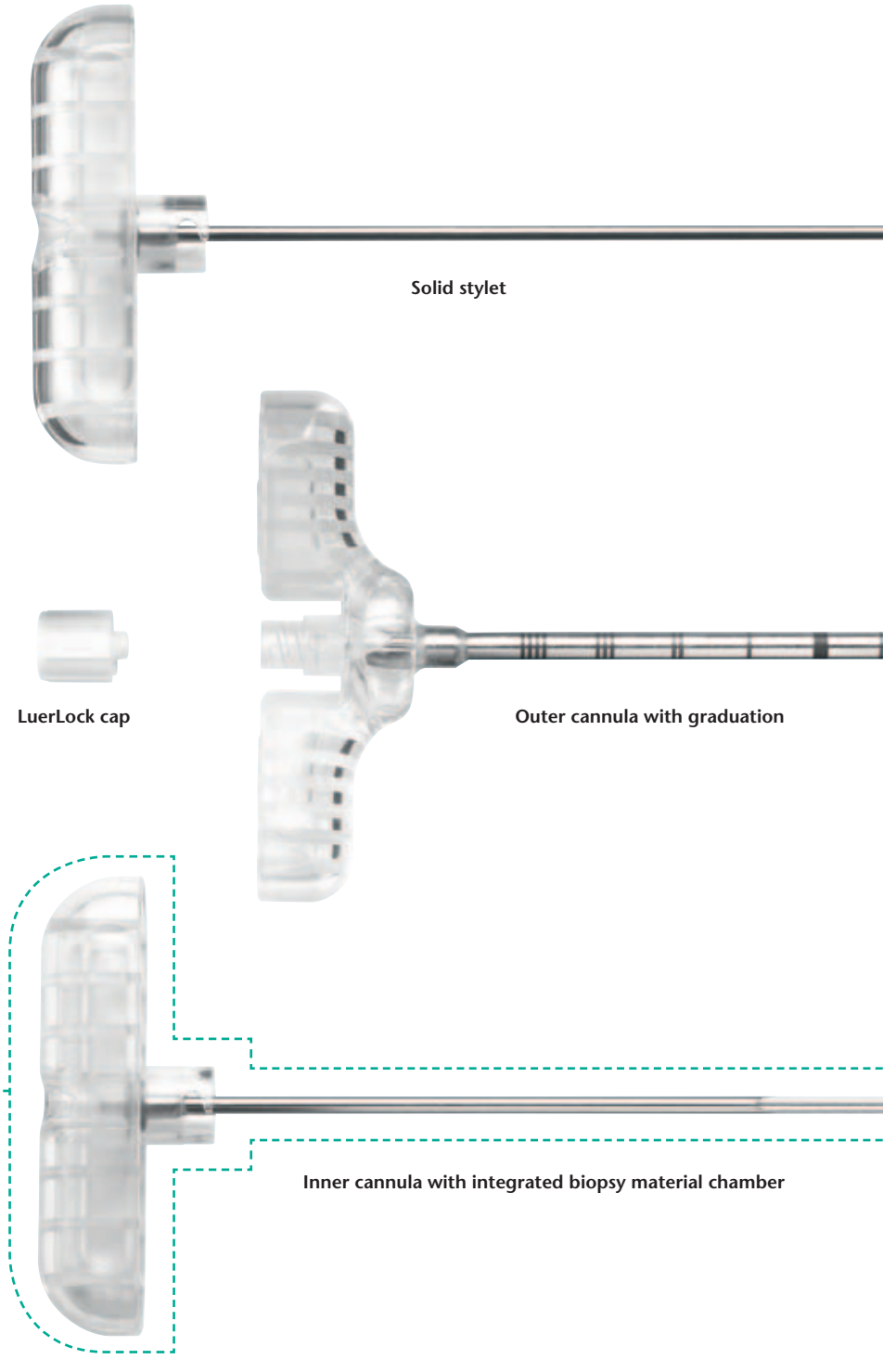
## *TrokaCut*

# *The complete system for bone marrow puncture*

*The TrokaCut puncture set of equipment from PAJUNK® is a cost effective complete system for the extraction of bone marrow samples. It is very easy to use during puncture and aspiration.*

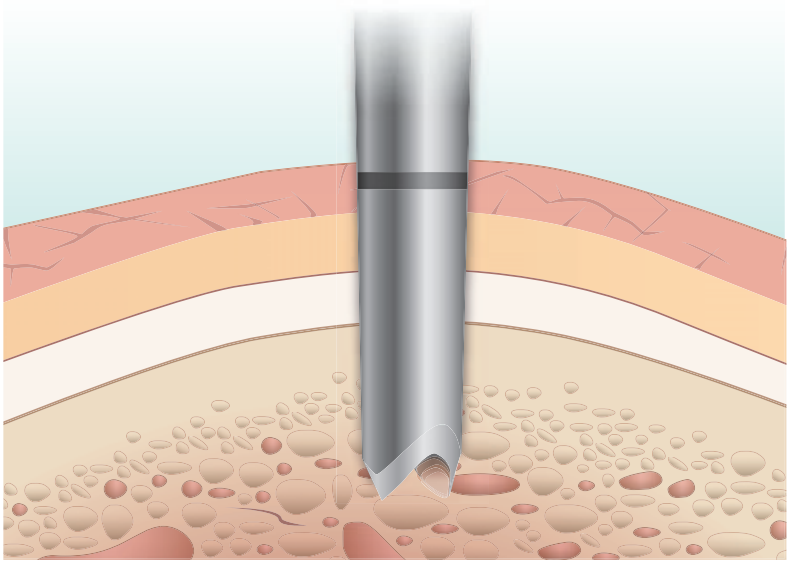
### *Single biopsy*

The TrokaCut set includes a stable full stylet with a sharp tip and bevelled hollow grind as well as an outer cannula with ejection stylet that are both provided with a graduation. The introductory aid covers the sharp tip of the outer cannula when extracting biopsy material and so prevents injuries.




### *Biopsy safety*

It is recommended to use an inner cannula with a biopsy material chamber for a safe biopsy. This inner cannula collects the sample when penetrating and can be pulled out for extraction without having to change the position of the outer cannula.



The outer cannula with its very sharp, wavelike tip penetrates the inside of the bone under rotary movements without problem.



Introductory aid

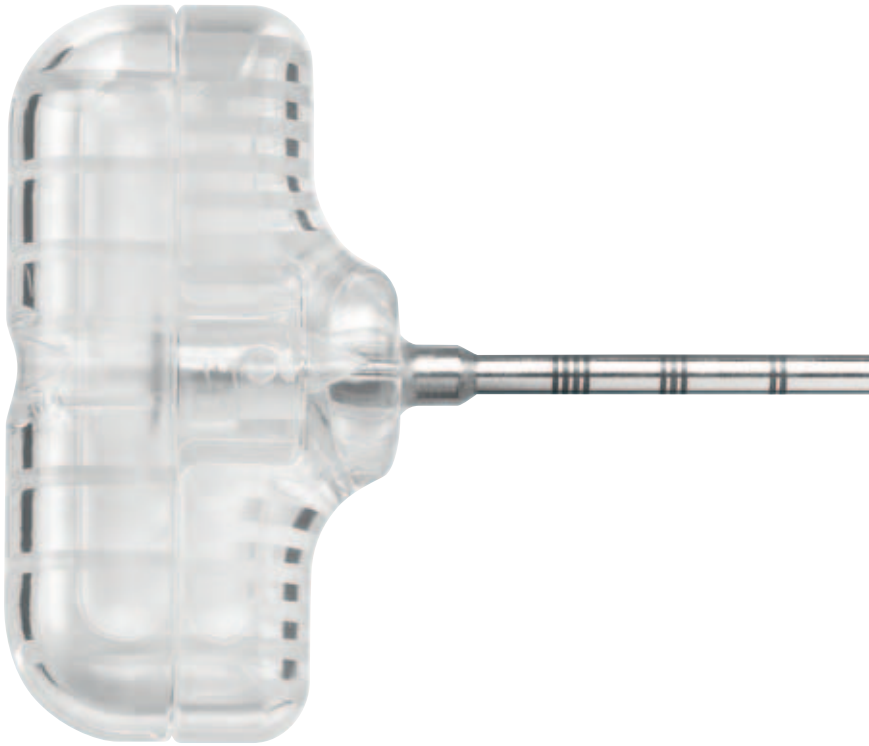
Ejection stylet with graduation

Integrated biopsy material chamber

## *The safe lock*

# *TrokaCut with bayonet lock*

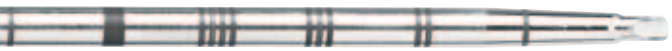
*The outer cannula is advanced together with the full stylet into the bone wall by turning clockwise and anticlockwise while applying firm and constant pressure. When it has penetrated and the resistance is reduced, the stylet is released from the bayonet lock, i.e. turned by 90° and pulled out. The outer cannula with its very sharp, wavelike tip continues to penetrate the inside of the bone under rotary movements without problem. The cannula tip is cylindrical and tapers towards the front. This eases collection and subsequent extraction of the sample. At the same time, its conical shape contributes to the tissue cylinder maintaining its structure during tissue extraction.*



***The essential features at a glance:***

- ➡ *anatomically shaped handle*
- ➡ *extremely sharp serrated tip of the outer cannula*
- ➡ *full stylet made of stainless steel with high stability*
- ➡ *tapered outer cannula for simplified sample extraction*
- ➡ *safe sample extraction by specially shaped cannula shaft*
- ➡ *aspiration connection with LuerLock connector*
- ➡ *specially shaped internal lumen*
- ➡ *bayonet lock*

**Bayonet lock**
**Full stylet and inner cannula are securely connected to the outer cannula using a bayonet lock.**



### Cannula tip with sharp bevelled hollow grind

➡ simplifies puncture of the pelvic crest in interaction with the rotary movements and pressure

### Sharp serrated tip of the outer cannula

➡ enables continued penetration of the outer cannula in the inside of the bone after removal of the full stylet and collection of the bone marrow sample

### Inner cannula with integrated biopsy material chamber

➡ additional biopsy safety and simple extraction

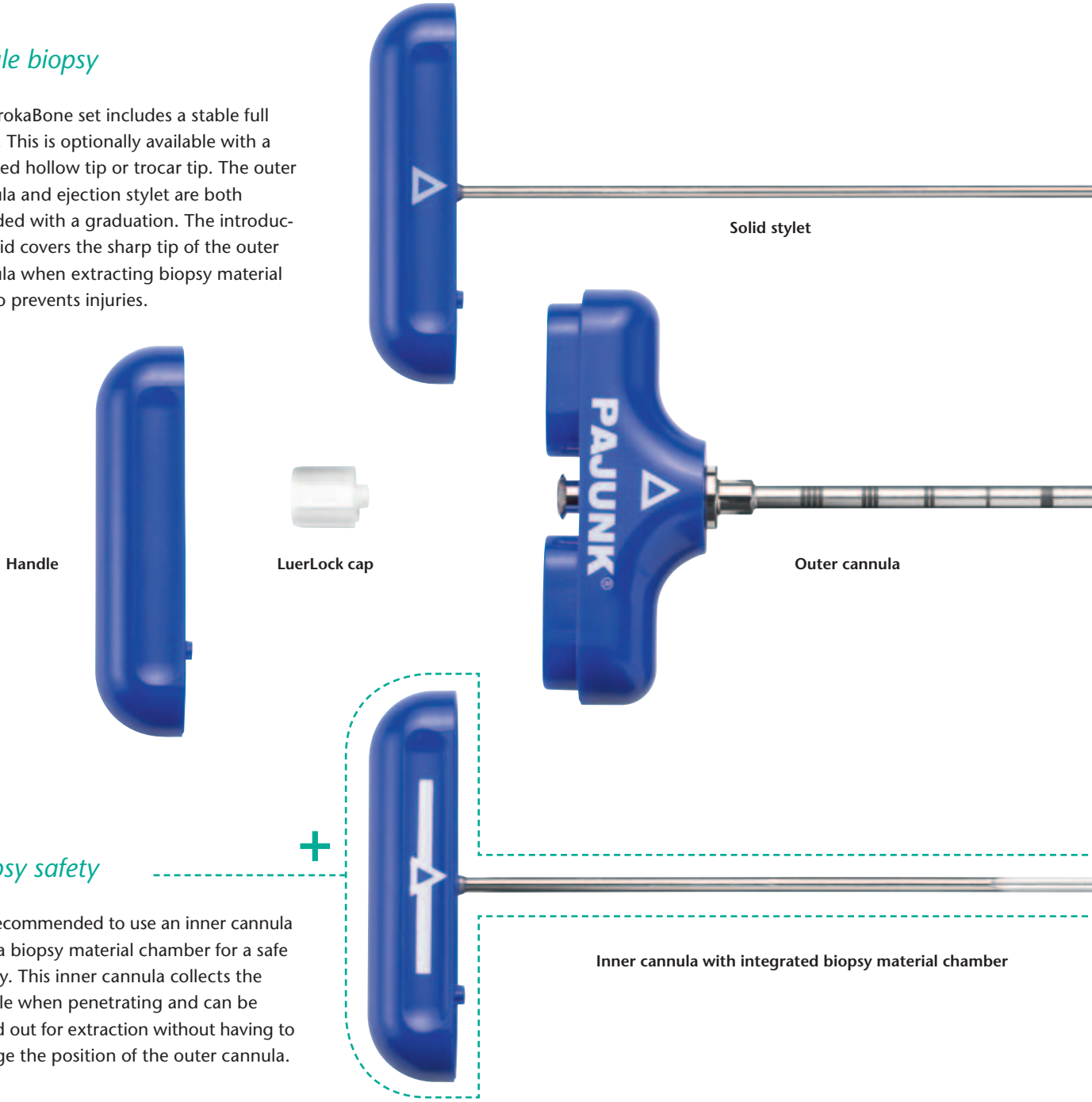
## *TrokaBone*

# *The robust complete system with stainless steel connection*

*The TrokaBone puncture set of equipment from PAJUNK® consists of a modular system for the extraction of bone marrow samples. This set is very easy to use for puncture and aspiration. Fitted with an ergonomic handle and manufacturer in robust stainless steel, TrokaBone is characterised by its high level of stability.*

## *Single biopsy*

The TrokaBone set includes a stable full stylet. This is optionally available with a bevelled hollow tip or trocar tip. The outer cannula and ejection stylet are both provided with a graduation. The introductory aid covers the sharp tip of the outer cannula when extracting biopsy material and so prevents injuries.




## *Biopsy safety*

It is recommended to use an inner cannula with a biopsy material chamber for a safe biopsy. This inner cannula collects the sample when penetrating and can be pulled out for extraction without having to change the position of the outer cannula.


Robust anchoring system made of metal with LuerLock connection.

Introductory aid

Ejection stylet with graduation

Integrated biopsy material chamber

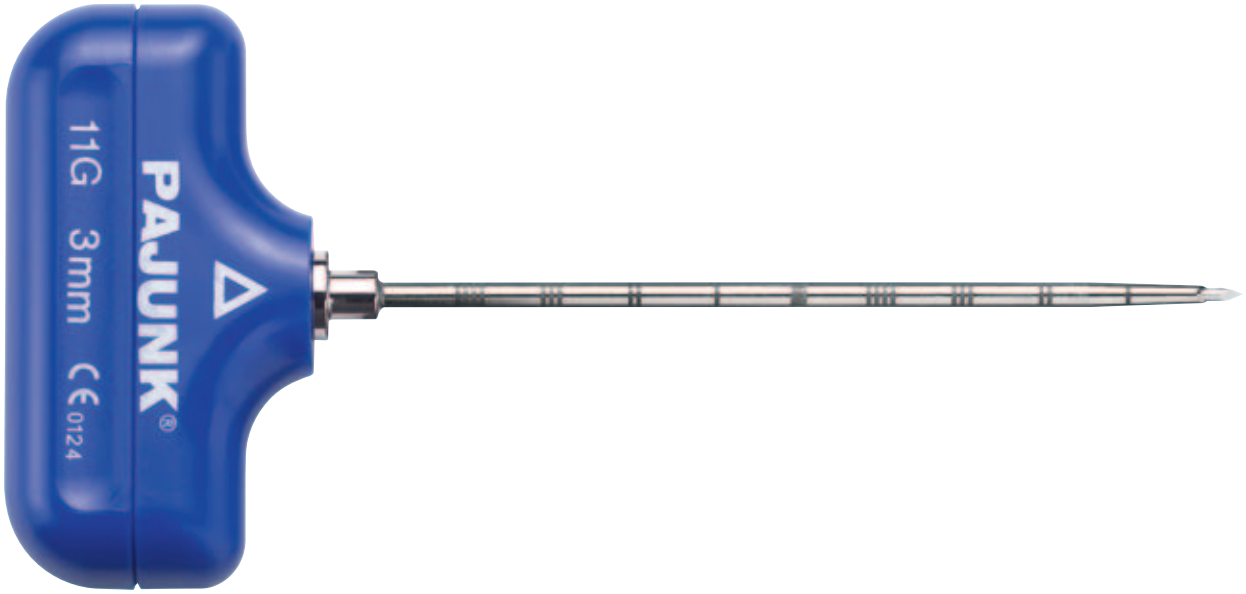
*TrokaBone*

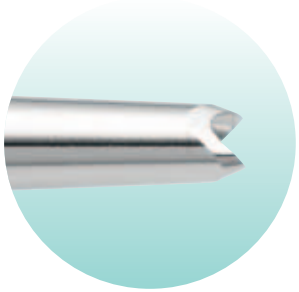
# *Biopsy cannula with alternative tip geometries*

*A bevelled tip or trocar tip is used to puncture at the pelvic crest. The puncture cannula is advanced forward into the bone wall under clockwise / counter clockwise rotation while applying firm and constant pressure. When it has penetrated and the resistance is reduced, the stylet is pulled out. The outer cannula has a very sharp, serrated tip. The cannula continues to penetrate into the inside of the bone under rotary movements without problem. The cannula tip is cylindrical and tapers towards the front. This eases collection and subsequent extraction of the sample. At the same time, its conical shape contributes to the tissue cylinder maintaining its structure during tissue extraction.*

***The essential features at a glance:***

- *anatomically shaped handle*
- *extremely sharp serrated tip of the outer cannula*
- *full stylet made of stainless steel with high stability*
- *cannula versions with bevelled tip, trocar tip and inner cannula*
- *tapered outer cannula for simplified sample extraction*
- *specially shaped internal lumen*
- *aspiration connection with LuerLock connector*



Tapered cannula tip, serrated tip

Cutting tip with bevelled hollow grind

Sharp tip with trocar grind

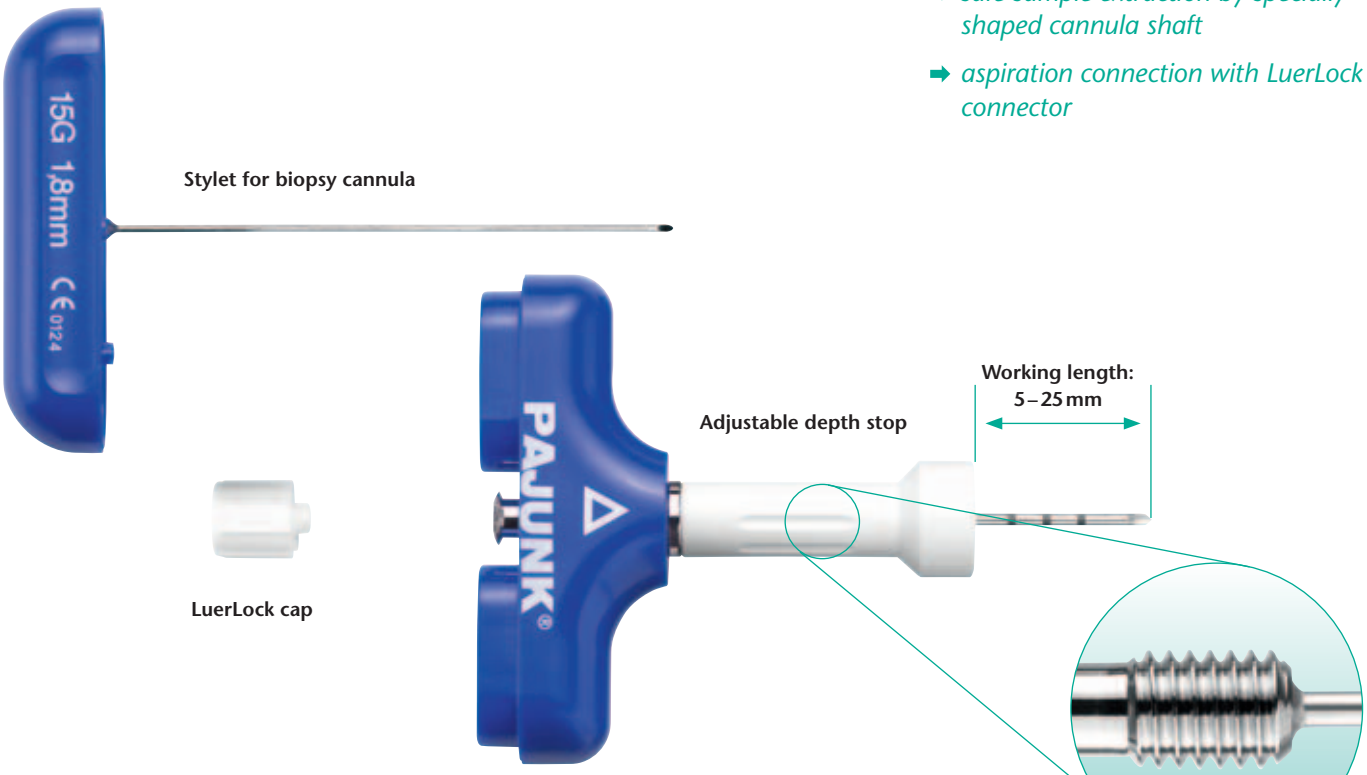
## *TrokaBone Sternal*

# *Puncture set of equipment for single biopsy*

*TrokaBone Sternal was developed by PAJUNK® for simple and safe aspiration of bone marrow from the pelvic and sternum region. The ergonomically shaped handle and the extremely sharp cannula tip guarantees ease of use during puncture and aspiration.*

***The essential features at a glance:***

- *anatomically shaped handle*
- *extremely sharp cannula tip*
- *puncture cannula made of stainless steel with high stability*
- *safe sample extraction by specially shaped cannula shaft*
- *aspiration connection with LuerLock connector*




Cannula tip with sharp grind

Precise fit grind between outer cannula and stylet

## TrokaCut

| Product | Size | Art. No. | PU |
|---|---|---|---|
| Set for bone marrow biopsy with bevelled hollow tip | 13 G x 100 mm (2.4 mm) | 1147-1C010 | 5 |
| | 11 G x 100 mm (3.0 mm) | 1147-1E010 | 5 |
| | 11 G x 150 mm (3.0 mm) | 1147-1E015 | 5 |
| | 8 G x 100 mm (4.0 mm) | 1147-1I010 | 5 |
| | 8 G x 150 mm (4.0 mm) | 1147-1I015 | 5 |
| Set for bone marrow biopsy with bevelled hollow tip and inner cannula | 11 G x 100 mm (3.0 mm) | 1147-6E010 | 5 |
| | 8 G x 100 mm (4.0 mm) | 1147-6I010 | 5 |

## TrokaBone

| | | Bevelled hollow tip | Trocar tip | |
|---|---|---|---|---|
| Product | Size | Art. No. | Art. No. | PU |
| Set for bone marrow biopsy | 13 G x 100 mm (2.4 mm) | 1145-1C010 | 1145-2C010 | 5 |
| | 11 G x 100 mm (3.0 mm) | 1145-1E010 | 1145-2E010 | 5 |
| | 11 G x 150 mm (3.0 mm) | 1145-1E015 | 1145-2E015 | 5 |
| | 8 G x 100 mm (4.0 mm) | 1145-1I010 | 1145-2I010 | 5 |
| | 8 G x 150 mm (4.0 mm) | 1145-1I015 | 1145-2I015 | 5 |
| Set for bone marrow biopsy with inner cannula | 11 G x 100 mm (3.0 mm) | 1145-6E010 | | 5 |
| | 8 G x 100 mm (4.0 mm) | 1145-6I010 | | 5 |


## TrokaBone Sternal

**Working length 5–25 mm**

| Product | Size | Art. No. | PU |
|---|---|---|---|
| Set for bone marrow biopsy in sternum region | 18 G x 50 mm (1.2 mm) | 1146-1D025 | 5 |
| | 17 G x 50 mm (1.5 mm) | 1146-1G025 | 5 |
| | 15 G x 50 mm (1.8 mm) | 1146-1K025 | 5 |
| | 14 G x 50 mm (2.0 mm) | 1146-1M025 | 5 |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