Design, manufacturing and trade of medical devices for the extremities

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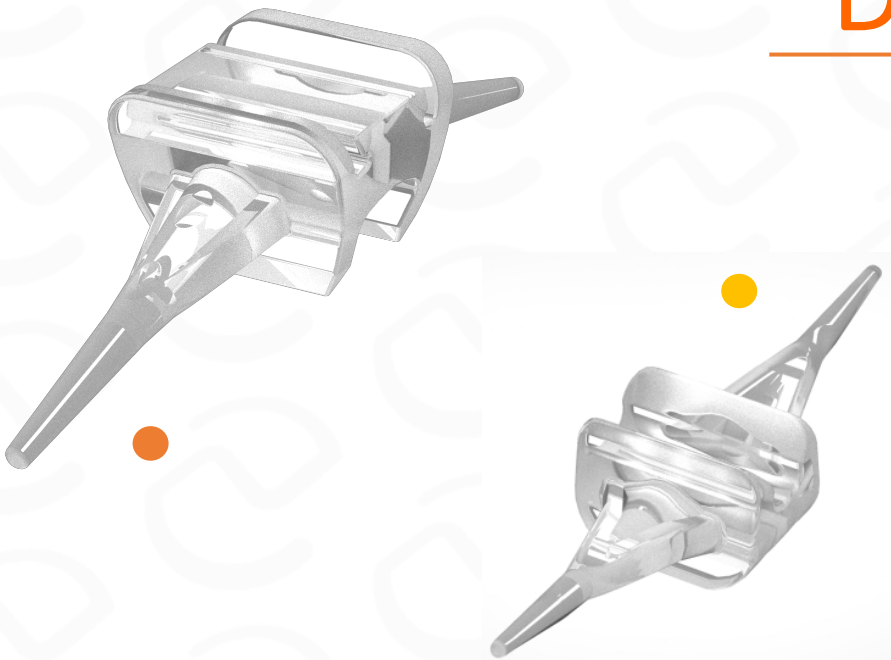
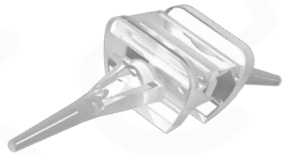
Digitalis



BRM Extremities



Digitalis

Silicone Spacers for MetacarpoPhalangeal (MCP) & Proximal InterPhalangeal (PIP) joints

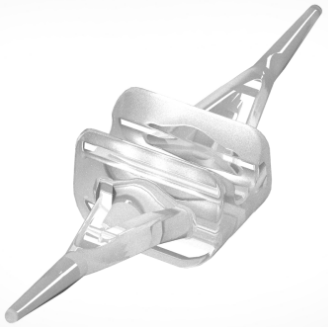
- ✓ Osteoarthrosis
- ✓ Rheumatoid arthritis
- ✓ Post traumatic arthritis

MCP

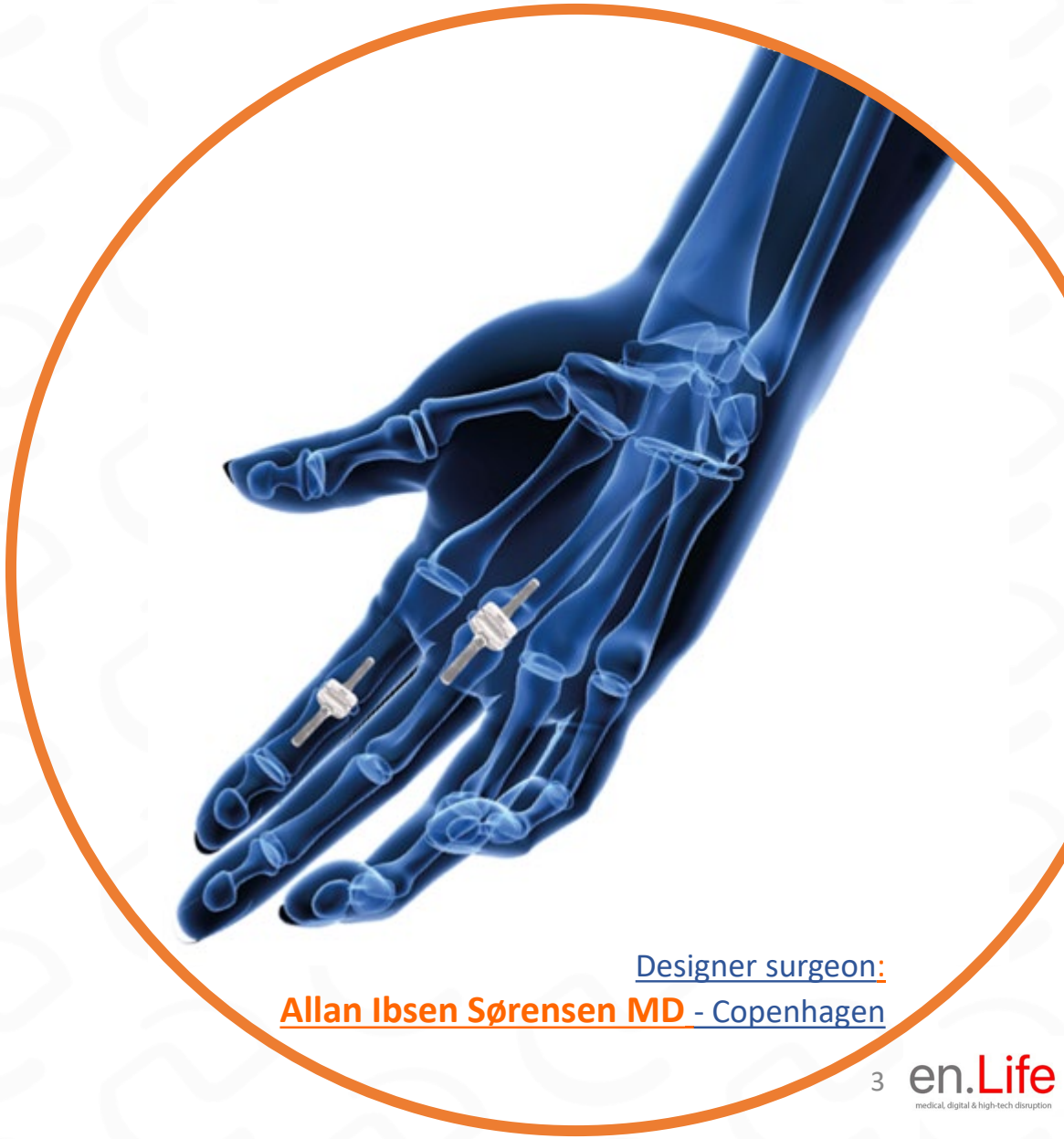
Available in 5 sizes

PIP

Available in 4 sizes



- ✓ Osteoarthritis
- ✓ Rheumatoid arthritis
- ✓ Destroyed articular surfaces
- ✓ Ankylosed joints or with limited range of motion
- ✓ Non-functional joint due to inadequate bony alignment



Designer surgeon:

Allan Ibsen Sørensen MD - Copenhagen

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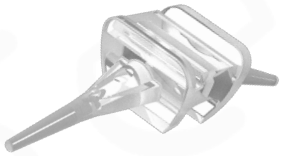

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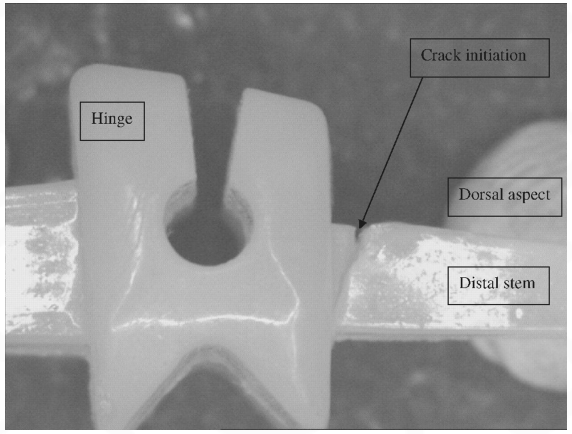
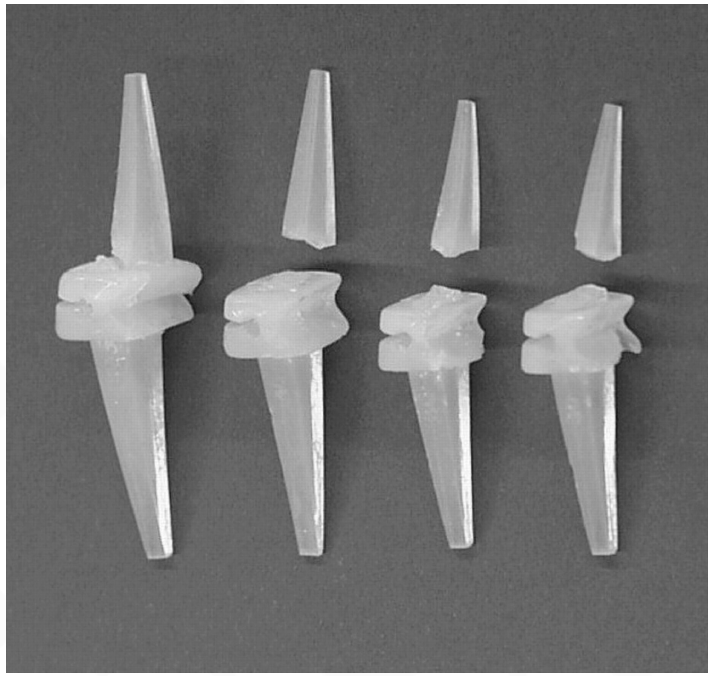
Design logic

1. Reduce the complications in the future

- **State of art**





JOYCE TJ. Analysis of the Mechanism of Fracture of Silicone Metacarpophalangeal Prostheses. Journal of Hand Surgery (European Volume). 2009;34(1):18-24. doi:10.1177/1753193408093808

Swanson	17 years	10 years
Implant fracture	58%	34%
Revision	83%	63%

Kaplan-Meyer survivorship

Seventeen-year survivorship analysis of silastic metacarpophalangeal joint replacement
Ian A. Trail and J. Martin and David Nuttall and John K. Stanley
The Journal of bone and joint surgery. British volume - 2004;86(7); 1002-6

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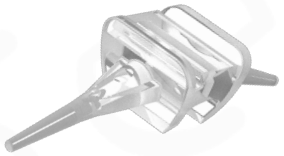

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Design logic

1. Reduce the complications in the future

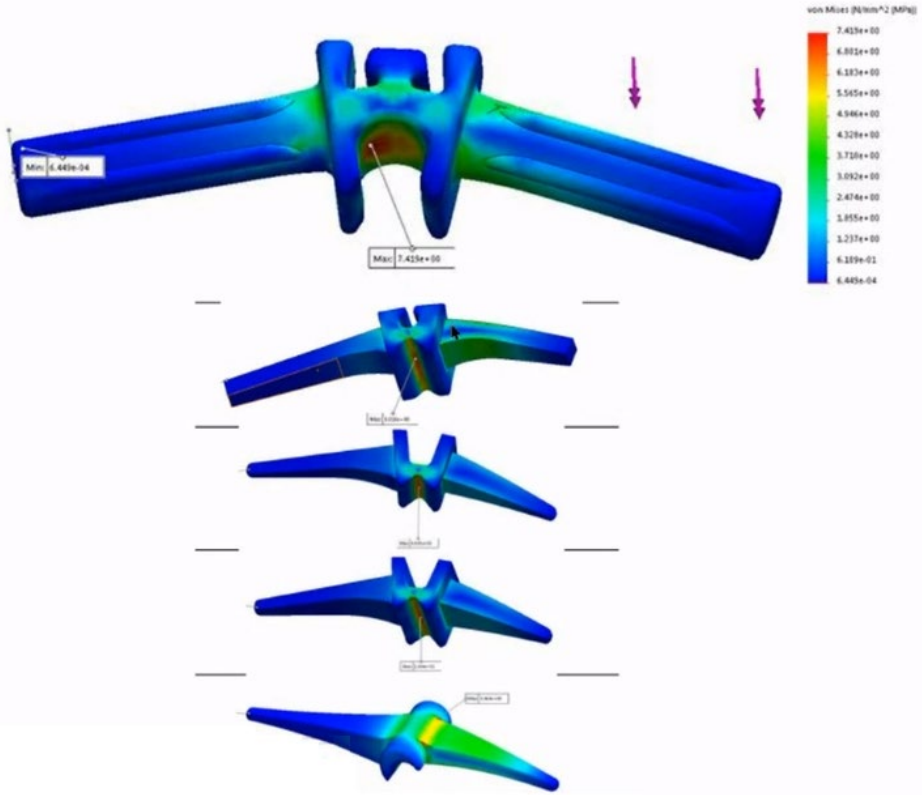
- **Comparison Stress test - FEM analysis**

Digitalis

Preflex, former Avanta

Neuflex

Swanson



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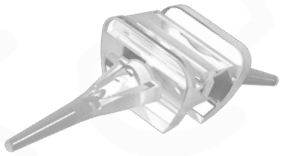

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Design logic

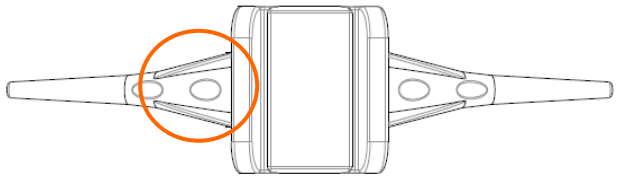
1. Reduce the complications in the future

➢ New design

→ Spacers made of NuSil MED 4735: last generation silicone (the fourth)

→ Hinge designed to reduce the stress when it is bended 0-90°
Dorsal **T** design to avoid the hyper-extension and strengthen the hinge

→ Rotation stability secured in the interface: at the hinge level, stems have a triangular section which helps to increase both mechanical resistance and rotational stability of the spacer



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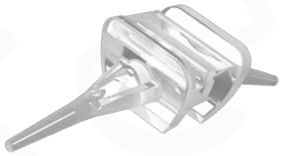
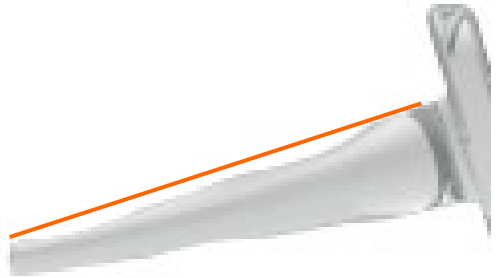


Design logic

1. Reduce the complications in the future

- **New design**

→ Stems with anti-rotational design: the proximal and distal part of the stems are cylindrical with the same diameter. This part has a slightly contoured surface, which minimize gliding out of the bony canal during bending



→ Thinner stems because there is not any lateral forces in the bony canal distal and proximal at the interface

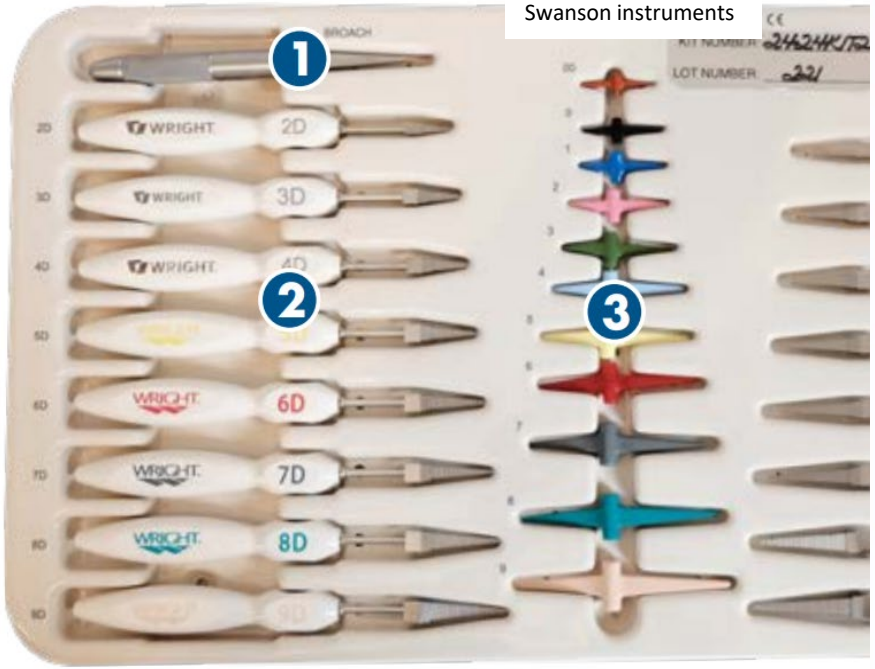
→ Same length and shape of proximal and distal stem

→ 15°(PIP) et 30°(MCP) hinge side's pre-bending angle to respect the normal finger position and avoid overstress of the silicon material

Design logic

2. Develop a new, simpler and more practical instrumentation

- **State of art**



Swanson instruments

Avanta - Sutter - Preflex MCP instruments

Design logic

2. Develop a new, simpler and more practical instrumentation

➢ **New design**

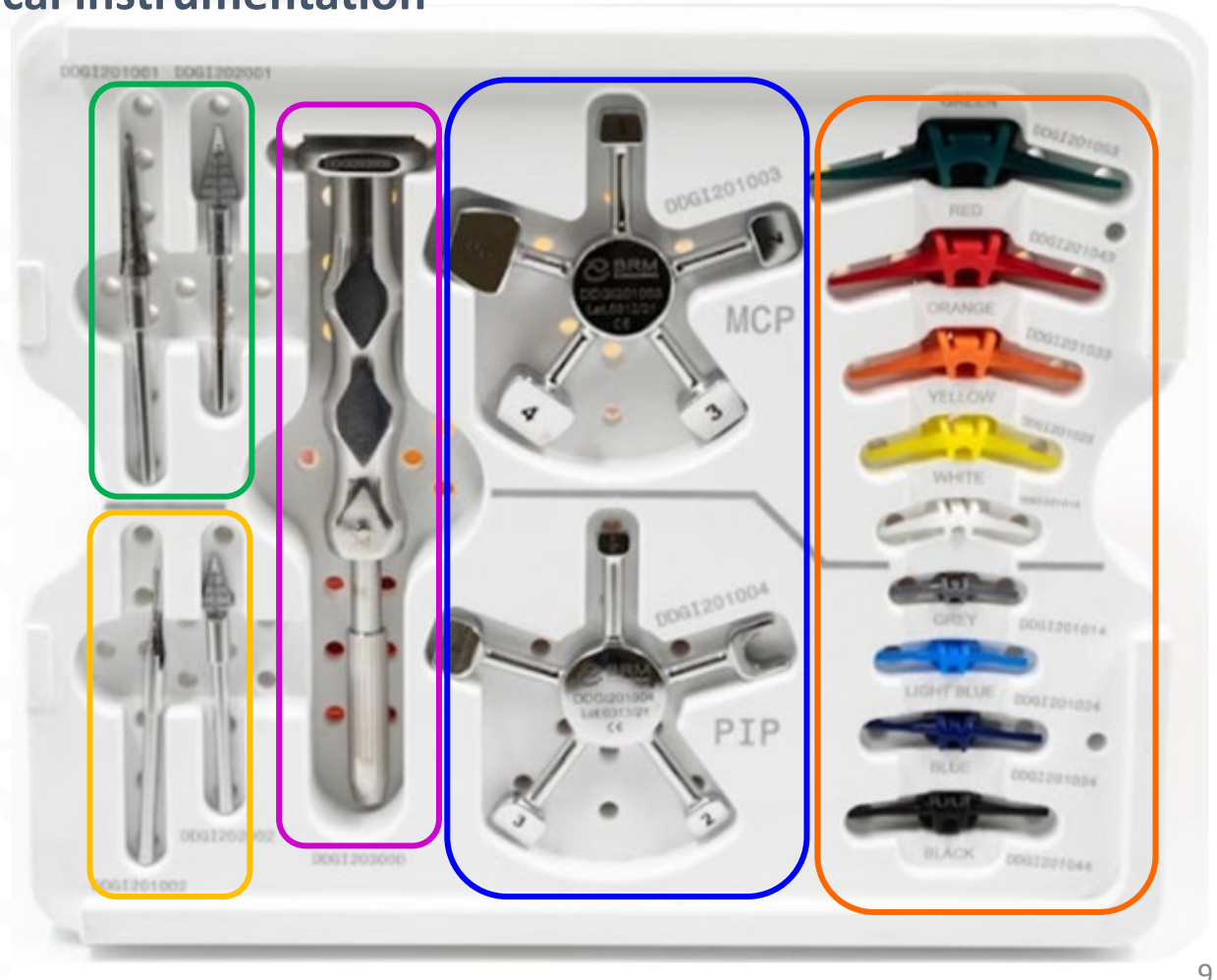
1 colored silicone trial for size (for final size selection)

1 multiplesize trial for PIP and 1 for MCP joint

1 handle

1 reamer and 1 rasp for MCP medullary canals preparation

1 reamer and 1 rasp for PIP medullary canals preparation



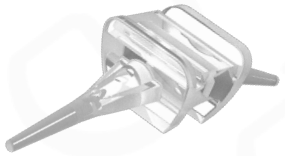
Surgical Technique

① Articulation exposure

Make a longitudinal incision along the MCP joint and expose the articulation, preserving as much as possible the capsule and the ligament.

② Articular surfaces resection

Use a micro-oscillating saw for resecting the metacarpal head at the distal end and the base of the proximal phalanx.



Digitalis - Surgical Technique

Surgical Technique

③ Size choice

Starting from the smallest size, use the test spacer to check and choose the one that best fits anatomically within the joint.

④ Preparation of the medullary canals

Use the reamer to identify the metacarpal and proximal phalangeal canals. Then use the rasp to prepare the relative medullary canals: advance until reaching the depth corresponding to the chosen size, indicated on the instruments.

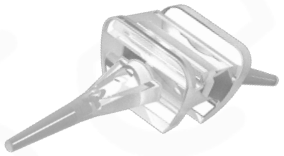
Surgical Technique

⑤ Final implant

Check again the correct sizing and the mobility of the joint using the trial spacer and insert the final implant.

⑥ Wound closure

Correctly replace and suture the extensor tendon and wrap the radial cap and sagittal fascia. Move the joint again to ensure there is no extensor tendon subluxation from 0 to 90 degrees of flexion.



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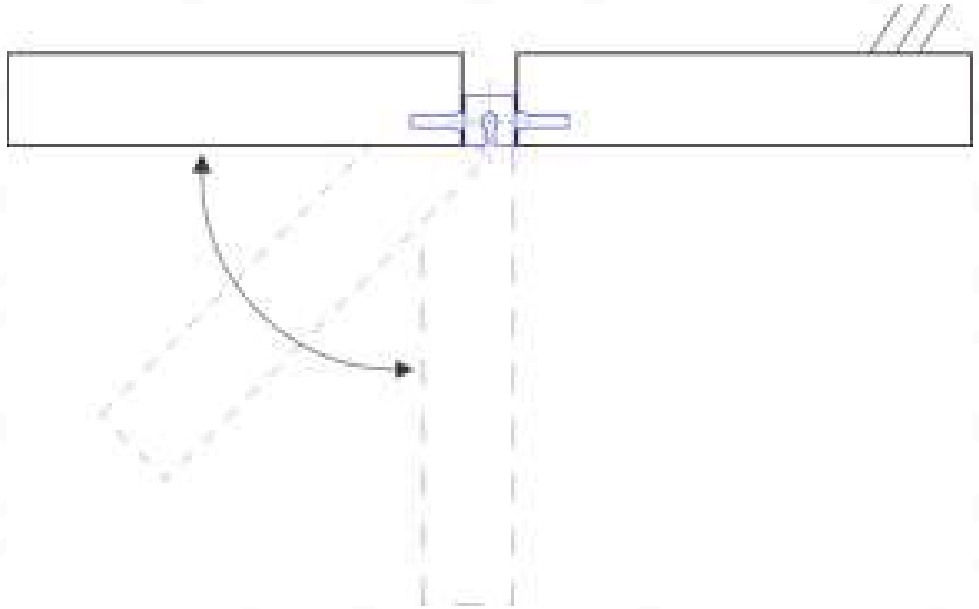
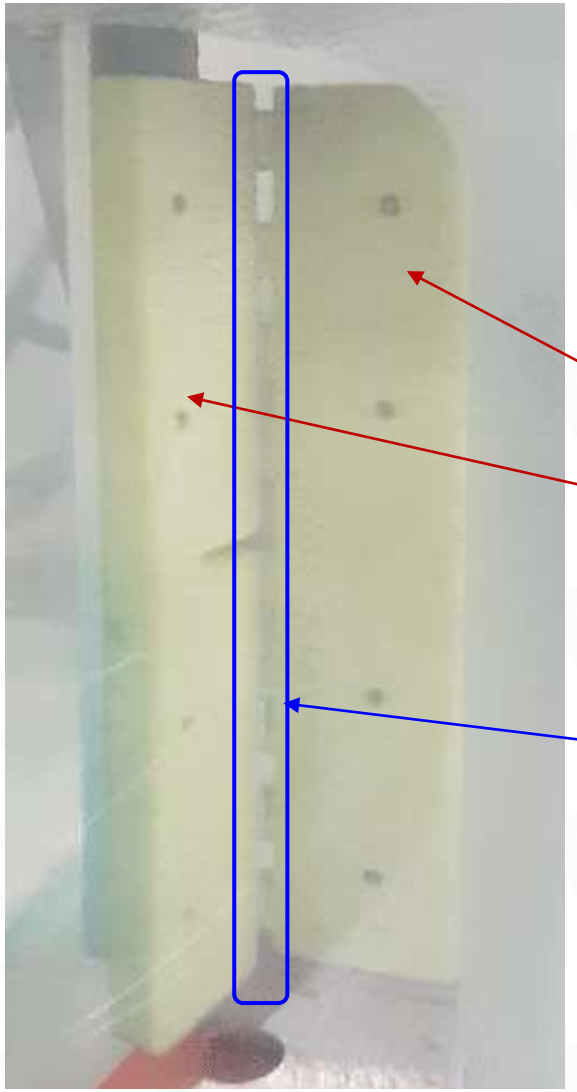
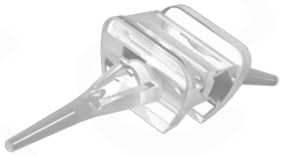
Mechanical Test



Placement and operating modality of the spacer during test





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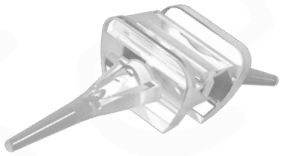
Test parameters:

- rotational movement of 90 degrees
- frequency: 1,2 Hz
- number of cycles: 5,000,000
- Environment:
  - saline solution composed by 50% deionized water and 50% PBS (phosphate-buffered saline)
  - pH = 7,2
  - T = 36 ± 0,5 ºC

Test results:

- all the samples have passed 5.000.000 load cycles and there was no failure or degradation on the implants



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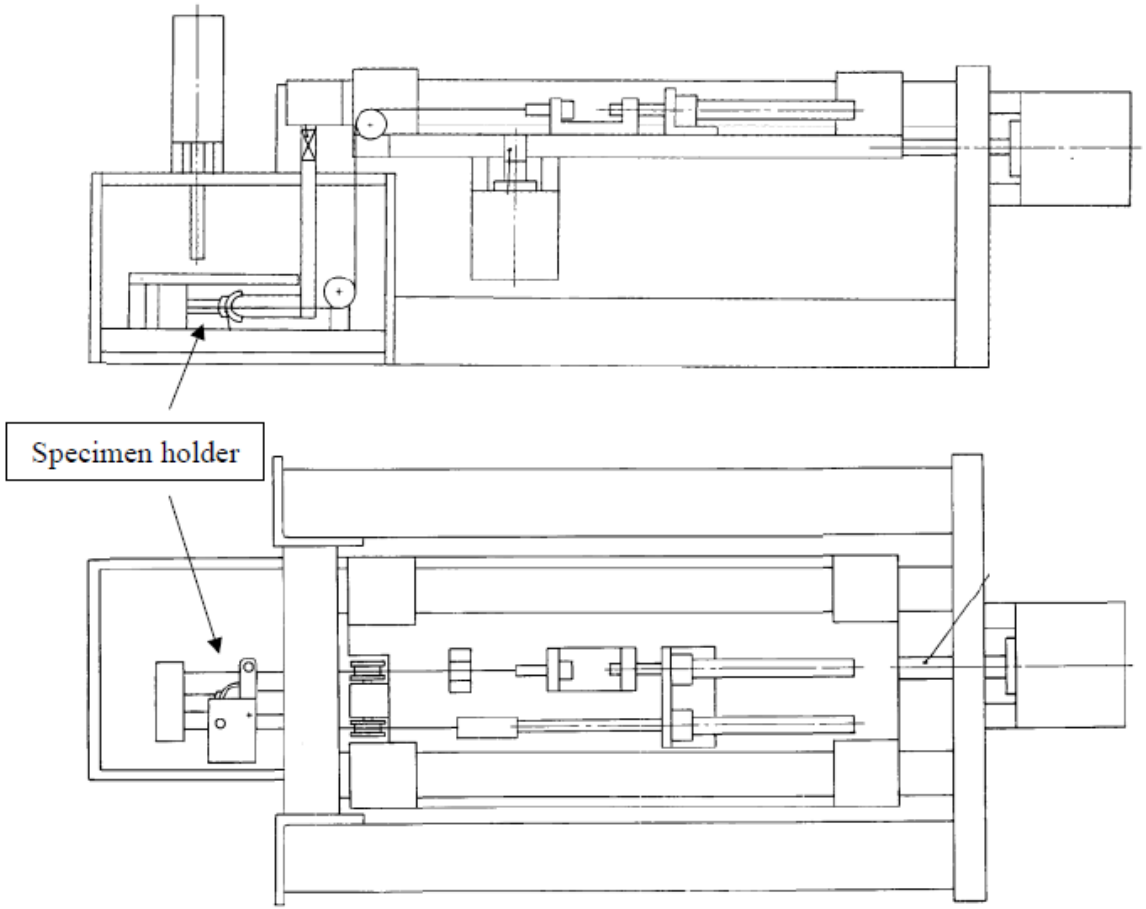
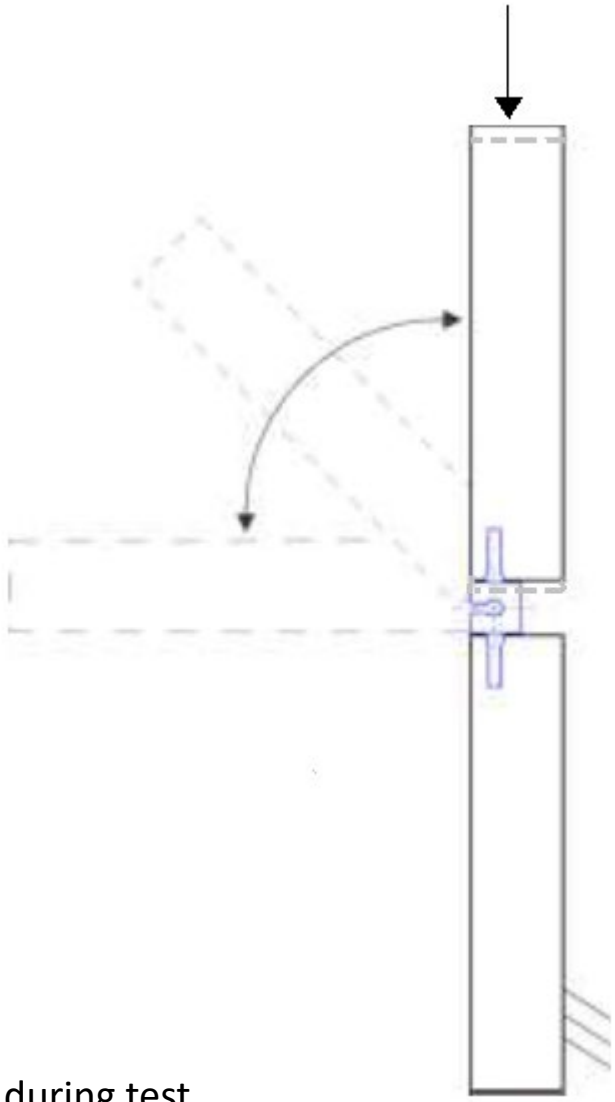
Mechanical Test: ASTM F1781 (2021)





Placement and operating modality of the spacer during test

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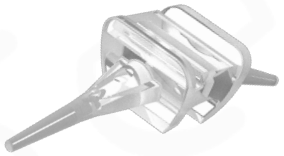

Digitalis

Test parameters:

- Rotational movement:
  - ✓ range: from -15 to 90 degrees
  - ✓ frequency: 1,667 Hz or 100 cycles/minute
  - ✓ number of cycles: 10,000,000
  - ✓ load: 10 N to 15 N
  - ✓ environment:
    - saline solution composed by 50% deionized water and 50% PBS (phosphate-buffered saline)
    - pH = 7,2
    - T = 36 ± 1ºC

- Axial movement:
  - ✓ pinch load: 100N
  - ✓ frequency: every 3000 cycles for 45s

Test results:

- all the samples have passed 10.000.000 load cycles and there was no failure or degradation on the implants

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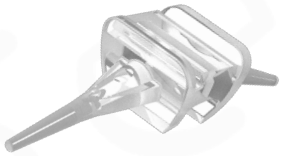

Digitalis

First results from Dr. Allan Ibsen Sørensen

→ Digit MCP 2, female, 49 years with rheumatoid arthritis

	Preop	8 weeks
Pain at rest, VAS (mm)	57	0
Pain in activity, VAS (mm)	100	
Grip strenght (% of contralat)	26	84
Extension (degrees)	18	18
Flexion (degrees)	76	62
Patient satisfaction grade (1-5)	5	2

Preop

Postop.

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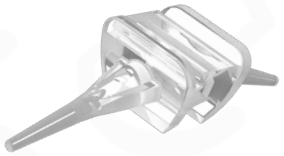
First results from Dr. Allan Ibsen Sørensen

→ Digit PIP 3, female, 71 years with osteoarthritis

	Preoperative	8 weeks
Pain at rest, VAS (mm)	90	2
Pain in activity, VAS (mm)	72	2
Grip strenght (% of contralat)		84
Extension (degrees)	0	18
Flexion (degrees)	75	62
Patient satisfaction grade (1-5)	5	2
Patient Score	30	65

Postop.



Digitalis

First results from Dr. Allan Ibsen Sørensen

→ Digit PIP 3, female, 65 years with osteoarthritis

	Preop	10 months
Pain at rest, VAS (mm)	80	0
Pain in activity, VAS (mm)	20	0
Extension (degrees)	100	20
Flexion (degrees)	60	90
Patient satisfaction grade (1-5)	5	1
Patient Score	29	81

Preop

10 months Postop.

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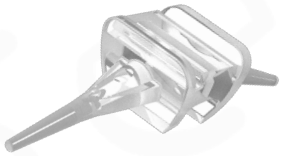

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First results from Dr. Allan Ibsen Sørensen

→ Digit PIP 2, female, 65 years with osteoarthritis

	Preop	8 months
Pain at rest, VAS (mm)	100	0
Pain in activity, VAS (mm)	100	0
Extension (degrees)	0	20
Flexion (degrees)	58	68
Patient satisfaction grade (1-5)	5	1
Patient Score	6	79

Preop

8 months Postop.

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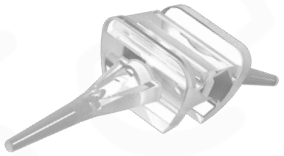


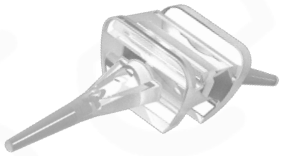
Digitalis

First results from Dr. Allan Ibsen Sørensen

→ Digit PIP 3, female, 56 years with osteoarthritis

	Preop	6 weeks
Pain at rest, VAS (mm)	0	10
Pain in activity, VAS (mm)	98	30
Extension (degrees)	0	30
Flexion (degrees)	38	58
Patient satisfaction grade (1-5)	5	2

Preop 6 weeks Postop.



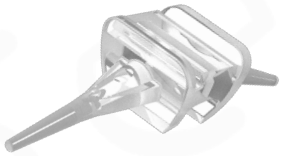
Digitalis

First results from Dr. Allan Ibsen Sørensen

→ Digit PIP 2, female, 56 years with osteoarthritis

	Preop	6 weeks
Pain at rest, VAS (mm)	0	10
Pain in activity, VAS (mm)	98	30
Extension (degrees)	0	30
Flexion (degrees)	34	46
Patient satisfaction grade (1-5)	5	2

Preop 6 weeks Postop.



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First outcomes from Dr. Allan Ibsen Sørensen

→ The implants are stable preoperatively and postoperatively

→ The instruments are precise and easy to handle

→ Radiographs shows that the implants are well aligned

→ Very good pain relief

→ ROM is good in a very early stage

→ Patient satisfaction is high in a very early stage

→ Longer follow-up is needed

BRM® Extremities

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