

# move! 93

*a new way of thinking about everyday life  
in medicine and in the clinic*

STIMULI FROM ORTHOPAEDICS AND THE PROFESSIONAL FIELD – FOR PHYSICIANS, SPECIALISTS AND EXECUTIVES

*Focus on science*

From the initial concept to  
the set of instruments



*Preservation in motion*

Affinis Short  
Number 1 in stemless shoulder  
endoprotheses



*From the professional field*

Skilfully thwarting  
mismatchers





# From the initial concept to the set of instruments

By Stefan Saladin, Head of Knee Development, Mathys Ltd Bettlach

*The growing success of endoprosthetic operations is based on more than just continuous improvements in implant design. It is first and foremost the user-friendly instruments – the orthopaedic surgeon's «tools of the trade» – that make the surgical procedure easier and facilitate the use of new surgical techniques.*

Minimally invasive techniques only became mainstream thanks to specially adapted instruments, and only with smart instruments that offer intuitive handling can pre-operative planning be translated into precise intra-operative procedures. The instruments' precision and function, as well as their problem-free re-processing, must be completely reliable over the course of many surgical procedures.

Before a modern surgical instrument can be used during an endoprosthetic procedure on a patient, however, it must first undergo numerous developmental stages and checks. At Mathys, the process always begins with the question:

### What does the user want?

As a result, the technical concepts for the later instruments are optimised right from the out-

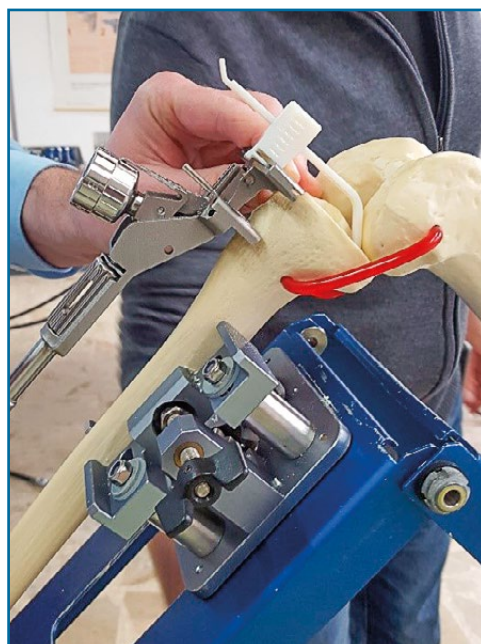
set in collaboration with clinicians and theatre personnel to ensure their compatibility and practicality in the workplace. This initially takes place rapidly and interactively, using instruments generated on 3D printers and on artificial bone in a laboratory setting. Practical ergonomics and operating theatre processes shape the design around the technical requirements of functional elements. After a few prototype cycles, this is how a promising instrument design comes into being.

Over the course of the development of the instruments, aspects such as dimensional stability, optimisation of manufacturability and inherent product safety are refined. This latter aspect means anticipating potential risks associated with their use and constructively implementing risk reduction-measures such as design improvements.

### Prototype series put to the test

At this stage, the instruments are produced as a prototype series and then comprehensively tested. If all of the dimensional and geometric specifications are met, each individual function of the instrument is verified under simulated practical conditions. Fatigue and wear tests are carried out and the instruments are artificially soiled and their ability to be cleaned and sterilised is scrutinised. The biocompatibility of all materials and production processes used are confirmed. Packaging is selected that, in turn, is tested for functional integrity with the instruments using transport tests.

Finally, practical user tests under simulated surgical conditions validate the design concepts. For this purpose, the instruments must be used by clinicians, operating theatre personnel and processing personnel who were



**Fig. 1** Ergonomics and optimisation of the functions of the design concept using artificial bone





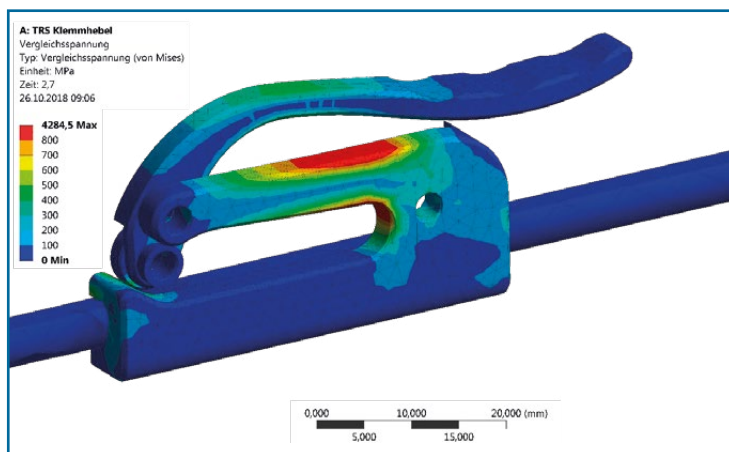
not involved in the development process, based on the product information provided. If the instruments can be used intuitively and confidently in line with their intended purpose, and if no problems or safety-related incidents are observed, then their suitability for use is deemed to have been confirmed.

**CE mark as a «birth certificate»**

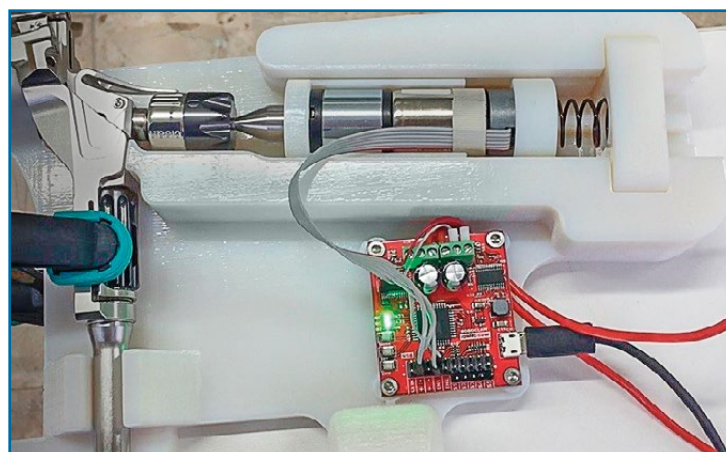
The tests carried out are evaluated from both a technical and clinical perspective and the re-

sults documented. Together with other documentary evidence, they form the contents of the instruments' technical documentation. This represents an important part of the development of any medical product. Specialists in the regulatory department then ultimately check that the products have been manufactured, checked and have documentation in full compliance with the applicable standards and regulations. If so, then the instruments are given their «birth certificate», the CE mark,

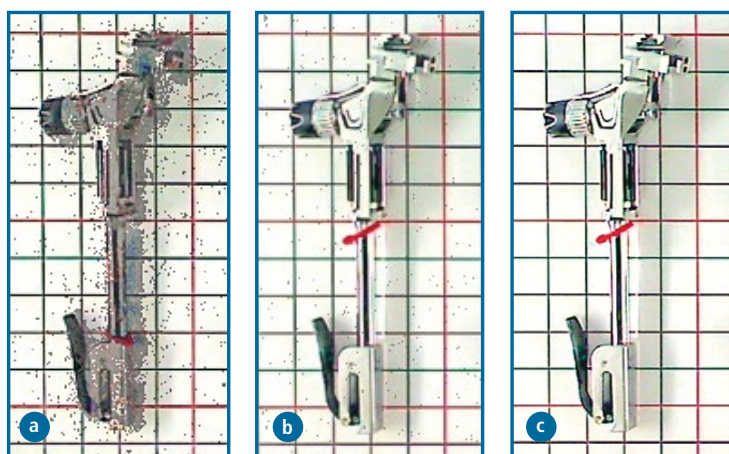
and are ready for distribution, user training courses and the first surgical procedures in clinical centres – all for the patient's benefit.



**Fig. 2** Stability simulation for the dimensioning of a clamping lever



**Fig. 3** Fatigue testing of a locking function on the instrument using a 3D-printed test specimen. Servo motors and software simulate instrument wear over the anticipated instrument lifecycle in the space of a few hours. The functionality must remain unimpaired even after many years of use and re-sterilisation.



**Fig. 4** Radionuclide images of an instrument, (a) after artificial soiling with blood and bone dust, (b) after manual pre-cleaning and (c) after final cleaning by machine. The blood tagged with radionuclides emits locally detectable radiation which highlights even microscopically small areas of contamination in areas that cannot be seen with the naked eye.



**Fig. 5** Simulated surgery under realistic conditions, allowing pre-clinical confirmation of the instrument's design and intra-operative workflows. The simulation includes a review of the user documentation, the preparation of the instruments by theatre staff, simulated surgery by the clinician and subsequent reprocessing of the instruments.

# Affinis Short – Number 1 in stemless shoulder endoprotheses<sup>1,2</sup>

*The latest registry data shows that the Affinis Short tops the list of the most frequently implanted stemless shoulder endoprotheses.<sup>1,2</sup> Implantation in just a few steps with simple instruments along with the long service life of the materials<sup>3</sup> and excellent clinical outcomes<sup>1</sup> are key to ensure its strong acceptance on the market.*

The Affinis Short is a stemless shoulder endoprosthesis with a design that allows restoration of glenohumeral geometry<sup>4</sup>.

The short stem has a large-pored titanium structure with a calcium phosphate coating, which promotes bone integration and contributes to good secondary stability.<sup>5</sup> Its metaphyseal anchoring is less invasive than with conventional stem prostheses.<sup>4</sup> The stem geometry allows bone-sparing revision, for example following a rotator cuff tear or an infection.

Humeral ceramic heads made in-house have been in clinical use at Mathys since 2000. Ceramic has a high degree of biocompatibility.<sup>6</sup> The size graduations of the implants allow a more precise reconstruction of glenohumeral geometry<sup>4</sup>. The glenoid is made up of the vitamin E-stabilised, highly cross-linked polyethylene vitamys. In combination with a ceramic head, this reduces polyethylene wear compared to conventional tribological pairings.<sup>4,7</sup> Because it is completely free of nickel, cobalt and chrome, the Affinis Short shoulder prosthesis is also suitable for patients who are sensitive to these materials.



The instruments for the Affinis Short are easy to work with. Resecting the humeral head facilitates access to the glenoid, allowing more precise implantation of the total prosthesis.

### The Affinis Short currently leads the way:

- The most frequently implanted stemless prosthesis in registries in Australia (AOANJRR)<sup>2</sup> and England (NJR)<sup>1</sup>
- Half the average revision rate in the NJR<sup>1</sup>
- Over 10'000 implanted worldwide since 2009<sup>4</sup>

With the Affinis Short, we are responding to users' needs and fulfilling the company's promise of «**Preservation in motion**».

<sup>1</sup> National Joint Registry for England, Wales, Northern Ireland and the Isle of Man. 15<sup>th</sup> Annual Report 2018; p. 166.

<sup>2</sup> Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR). Hip, Knee & Shoulder Arthroplasty: 2018 Annual Report; p. 326-327.

<sup>3</sup> Lerf R, Zurbrugg D, Delfosse D. Use of vitamin E to protect cross-linked UHMWPE from oxidation. *Biomaterials*. 2010;31(13):3643-8.

<sup>4</sup> Mathys data on file

<sup>5</sup> Schwarz ML, Kowarsch M, Rose S, et al. Effect

of surface roughness, porosity, and a resorbable calcium phosphate coating on osseointegration of titanium in a minipig model. *J Biomed Mater Res A*. 2009. 89(3):667-78.

<sup>6</sup> Barnes DH, Moavenian A, Sharma A, Best SM. Biocompatibility of Ceramics. *ASM Handbook*, 2012. 23

<sup>7</sup> Beck M, Delfosse D, Lerf R, et al. Oxidation Prevention with Vitamin E in a HXLPE Isoelastic Monoblock Pressfit Cup: Preliminary Results. In: Knahr K (ed.) *Total Hip Arthroplasty*. Heidelberg: Springer, 2012; p. 21-31.

## Team training on virtual patient

The American company Osso VR is enabling surgeons and doctors in training to practise their surgical techniques using virtual reality (VR). Operations are simulated on a virtual patient, with operative steps and procedures taught as realistically as possible.



Step-by-step explanations displayed via VR goggles guide surgeons through the virtual surgery. Team mode allows group training, even if the individual members of the team are not all in the same place. This allows surgeons or hospitals to offer training on a new technique or product in a single session involving multiple participants or a theatre team, for example. In addition to the learning effect, Osso VR also promises economic advantages, since training costs are lowered and sources of error can be reduced. Virtual surgeon training is already in use in numerous hospitals and is compatible with all common PC-VR goggles.

Find out more at [ossovr.com](http://ossovr.com)





# Skilfully thwarting mismatchers

*In NLP (neuro-linguistic programming), someone who is always looking for mistakes, has something negative to say about everything and counters every argument with «Yes, but ...» is known as a «mismatcher».<sup>1</sup> Having this type of person on your team may well be challenging, but it is not necessarily a bad thing.*

Mismatchers are almost predestined to pick up on mistakes. The problem comes when mismatchers work behind the scenes, creating issues in the background and cleverly playing colleagues and supervisors off against each other, manipulating them for their own purposes. The examples below provide a few pointers to help hospital managers spot manipulative mismatchers and offer ideas on how best to deal with them:<sup>2,3</sup>

### «I won't be able to manage it... could you maybe do it?»

Essentially, there's nothing wrong with a colleague or member of staff asking for help. That does not mean that they should simply take control of the situation and have you do their work for them. Some colleagues, however,

have perfected the art of «delegating upwards». Under the guise of wanting to do everything right wherever possible, the task – for example organising a meeting – is quickly delegated to you.

**Tip:** Counter with a friendly, «I'm sure you'll find a way to manage it.» If the employee really isn't able to complete the task, offer to show them how to do it rather than simply taking the task off them.

### «I can offer you three alternatives...»

If a mismatcher wants you to make a specific decision, they will cleverly offer you three solutions. At first glance, it looks like you have a choice. However only one of the suggestions is actually helpful or practicable. If the employee

is pursuing the goal of you hiring his friend from university, for example, he will recommend three candidates to you: a) his friend, b) someone unqualified and c) someone who is over-qualified.

**Tip:** Pick up on the mismatcher's intentions: «Let's be honest. You prefer person A. He's the only one really in the frame – the others aren't suitable.» And then say, «I need three real alternatives.» This allows you to make it clear that you have seen through his trick and cannot be manipulated.

### «I told you about it already...»

Sometimes, a mismatcher wants to hide an unpleasant or uncomfortable fact from you, for example that there have been complaints from patients about him. In order to avoid the accusation of having withheld information, he will use a concealment tactic: he will send you an e-mail with a subject line that you might well ignore, such as «Background information». Or he will bury the unpleasant information on the penultimate page of a long and boring report, in the hopes that you will not notice it.

**Tip:** Request that long documents be summarised on a maximum of one page. Make it clear that you will hold the author responsible if this one-pager leaves anything out that is clearly important.

### «Did you know we have a problem?»

If a mismatcher does not like the direction in which a team meeting is going, he will do everything he can to change the subject. He will address a problem that is guaranteed to draw your attention, such as increased post-operative infection rates. He might spread a rumour for this purpose: «Did you know that hygiene regulations are not being followed on our ward?»

**Tip:** Deflection manoeuvres only work if you are willing to go along with the change of



subject. Therefore, there should be an agenda for each meeting, which everyone present must stick to. If someone brings up a topic that is not on the agenda, postpone it: «You've mentioned an important problem there. Let's talk about that another time.» At some point, the mismatcher will realise that his tactic is not working.

Once you have revealed the mismatcher on your team, it is important to react immediately. Call a performance critique between the two of you early on, in which you factually and clearly address his behaviour. **Our checklist of «7 tips on how to provide fair critique» may be helpful for you.**

### Sources

- <sup>1</sup> McDermott I, O'Connor J. Practical NLP for Managers. Gower Pub Co. 1997.
- <sup>2</sup> James G. How to Handle a Manipulative Employee. Inc. 01.11.2012. [Available at <https://www.inc.com/geoffrey-james/how-to-handle-a-manipulative-employee.html>] Accessed on 15.10.18.
- <sup>3</sup> James G. 4 Ways That Employees Manipulate Bosses. Inc. 21.02.2013. [Available at <https://www.inc.com/geoffrey-james/4-ways-that-employees-manipulate-bosses.html>]. Accessed on 15.10.18.

## Download

The checklist containing «7 tips on how to provide fair critique to employees» is available for you to [download](#)



## Further reading



Robert B. Cialdini  
**Pre-Suasion: A Revolutionary Way to Influence and Persuade**  
 Simon & Schuster;  
 Reprint edition. 2016.

Amy Cooper Hakim, Muriel Salomon  
**Working with Difficult People**  
 TarcherPerigee.  
 2<sup>nd</sup> revised edition; 2016.

Georg K. Simon  
**In Sheep's Clothing: Understanding and Dealing with Manipulative People**  
 Parkhurst Brothers Publishers Inc.  
 2<sup>nd</sup> edition; 2010.

## Masthead

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