BAAT

BAAT projects over the years

1999
Vascular Prosthesis
Interbody Fusion Device
Scoliosis Orthosis
Orthosis Knee Joint
Stable Prosthetic Knee Joint

2000
Staple Remover
Laminar Hook Fixation for Thoracal Spine
Nitinol Spinal Rod
Vertebral Jack Tool for Fractures
Spinal Cage Inserter
Sit-to-Stand Aid
Coronary Staple
Epicondylitis Orthosis

2001
Rib Corrector
Orthosis Time Indicator
Foot Lifter
Distal Interlocking Screw Guidance System
Implantable Nitinol Scoliosis Correction System
3D Endoscope
Wrist Joint Replacement
Wrist and Finger Joint Replacement
Laparoscopic Forceps

2002
Scoliosis Orthosis 2nd Gen.
Spinal Cage
Fluid Dispenser
Dynamic Finger Splint
Anterior Cruciate Ligament Replacement
Heating Device for Lavage System
Club Foot Brace
Orthosis Ankle Joint
Calibration Instrument for Stereo Radiography
Scoliosis Measurement Device
Femoral Neck Fracture Fixation Implant
Segmented Scoliosis Correction Implant

2003
Arteriotomy Device
Patient Mover
Intramedullary Leg Lengthening Device
Active Revalidation
Hip Orthosis
Fragment Fixation System
Prosthetic Knee
Prosthetic Foot
Proximal Anastomosis Device
Spinal Cage Inserter
Vertebral Jack Instrument
Wrist Orthosis
Ophthalmologist Auxiliary Instruments
Hip Abduction Brace

2004
Posterior Spinal Fixation System
Hydrogel Dispenser
Patient Positioning for Fetal Heart Monitoring
Diabetic Foot Toolbox
Ophthalmic Diagnostic Tool
Intervertebral Distractor
Mono Hinge Orthosis
Nitinol Spinal Rod Controller
Marker Insertion Tool
Injection Molds for Orthotic Hinge
Knee Orthosis Hinge
Production Tool Coronary Staple
Nitinol Spinal Rod
Spinal Reposition Instrument
Spinal Navigation Pointer
Pedicle Location Instrument

2005
Spinal Disc Space Reamer
Knee Orthosis Hinge 2nd Gen.
Regulatory Support Spinal Posterior Fixation System
Posterior Spine System
Posterior Spine 2 Bar System
Patellofemoral Replacement Instruments
Artificial Spinal Disc
Hip Articular Surface Replacement Guide Instrument
Bone Cement Mixer
Bistable Knee Brace
Anterior Cervical Fixation System
Ankle Joint Orthosis 2nd Gen.
Large Range Motion Platform
Anterior Buttress Plate
Anterior Spinal Fixation System
Anterior Approach Spinal Fixation Plate
Minimally Invasive Assisted Surgery Robot Arm
Minimally Invasive Spinal Reposition Instrument
Bone Graft Impactors

2006
Hip Cage
Cervical Fixation Instruments
Pedicle Anchor Spine
Intramedullary Fracture Nail
Semi-Rigid Posterior Spinal Fixation
Pedicle Screw Lock
Metacarpophalangeal Prosthesis
Dynamic Posterior Spinal Correction System
Interbody Fusion Device Trial Sizers

2013
Osseointegration Adapter
Minimally Invasive Spinal Dilators
Cervical Disk Prosthesis
Assembly Tools for Surgical System
Minimally Invasive Pedicle Anchor
Trans Discal Spinal Screw Fixation System
Double Mobility Acetabular Cup
Anterior Spinal Distraction Device
Curved Bone Cement Applicator
Shoulder Joint Replacement
Total Knee Replacement
Re-usable Instruments Design for Reprocessing

2014
Supra Condylar Plate System
Orthopedic Instruments
Total Knee Replacement Instrument Set
Total Hip Replacement
Regulatory Support Tibial Fracture Plate
Shoulder Brace
Knee Distractor
Sterile Packaging for Knee Implant
Total Hip Replacement Instrument Set

2015
Knee Loading Research Device
3D Printed Custom Devices
Vertebral Cages
Brace
Scoliosis Device
Knee Implant Line
Compression Bandages
Club Foot Orthosis
Spinal Orthosis
Spinal Cage System
Spinal Pedicle Screw System

2016
Osseointegration Femoral Prosthesis
Regulatory Support Orthotics
Pelvic Fracture System
Spinal Facet Joint Fusion Device
IP Generation Expandable Cages
Hybrid Spine Jack
Interbody Fusion Cages
Market Mapping and Concept Generation Active Orthotics Line
Concept Generation Dynamic Spinal Cages
Implantable Insulin Pump

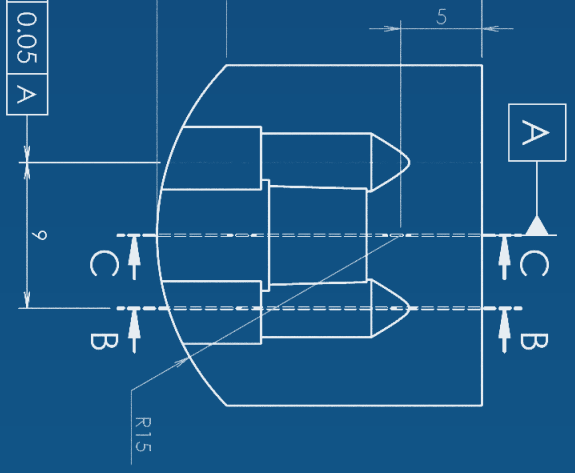
2017
Artificial Meniscus Implant and Instruments
Expandable Lateral Spinal Cage
Anterior Spinal Correction System

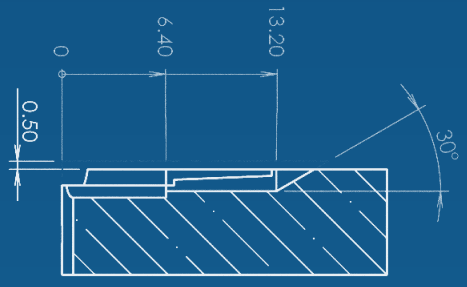
2018
Cage Line Extension
Spinal Cage Portfolio
Cervical Facet Fusion System
Compression Brace
Posterior Spinal Fixation System
Spinal Revision System
Finger Joint Prosthesis
510k 3D Printed Interbody Fusion Device
Cervical Spinal Instruments

2019
Bone Substitute
Minimally Invasive Interbody Fusion Device
Customized Implants
Spinal Cages
AutoGraft Applicator
Knee Cartilage Repair Instruments
Shoulder Implant
Patient Specific Implants
Spinal Cages MDD to MDR
HydroGel Applicator
Arm Support
Wound Drainage System
Innovation Scan Medicinal Cannabis
Interbody Fusion Devices
Disposable Instrument Set
Redesign Brace
Design Spine Fusion System
Knee Balancer

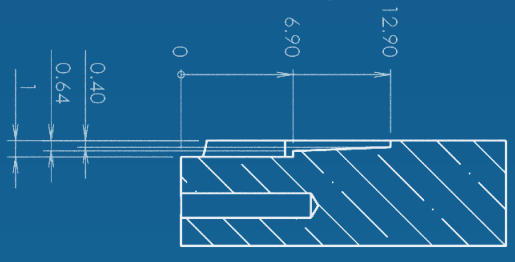
2020
Medicinal Cannabis Vaporizer
Nerve Growth Inhibition Device
Design Spinal Cage
Rotator Cuff Repair Implant and Instruments
Compression Socks
Medicinal Cannabis Grinder
Adjustable Interbody Fusion Devices
Regulatory Support AED
Validation Blood Penetration Tester
Regulatory Support MDR Transition Spinal Implants
Ceramic Knee Prosthesis and Instruments

2021
Pediatric Scoliosis System
Scoliosis Measuring Brace
Compression Nail
Bioresorbable Spinal Implants
Intramedullary Leg Lengthening Device
Lower Arm and Hand Orthosis Prototyping
Innovation Scan Bioresorbable Material





SECTION B-B



SECTION C-C


BAAT


1937
1907
1957
1927
A04
P2

Preface

Twenty-five years ago, Gert and I set out with one main goal: to have fun while making meaningful products. To finish Gert's scoliosis orthosis and then see from there. We wanted to bring high-tech solutions to orthopedics because, in our eyes, some innovation was overdue. From the start, we committed to creating products that would bring real benefits to patients, customers and ourselves. A philosophy that became our name: BAAT (benefit in Dutch).

For our tenth anniversary, we put together a small photo book to capture memories from those early years. Now, fifteen years later, I want to reflect again on all we've accomplished: 383 medical products developed for 185 (inter)national customers and the fact that BAAT has grown into a team of 45 incredible people, all working passionately on projects that matter. This anniversary book you hold, showcases a small selection of the many challenging projects, great customers, and collaborations that have defined our journey—an overview of a quarter century of BAAT.

This book is also a gift to Gert, my partner in crime, without whom BAAT wouldn't exist. Gert. I could not have asked for a better partner and friend in good times and bad. Never an unkind word between us, and never did we fail to find a solution to a problem. Never a dull moment. We could fill another book with those stories.

I hope that while you browse through these pages, you'll see the appreciation for our entire team, past and present—because together, we have made BAAT what it is today: A company we are proud of. I would like to name a few of this incredible team: The first generation, our pioneers — Allard, Huub and Martijn — who helped us lay the foundation of dedication and compassion that BAAT is known for. Then, the second generation — Vincent, Ryelle and Maarten — for their inspiration, enthusiasm and fresh perspectives. And the third generation — Odmar, Bernic, Jasper and Dorien, our 'new experts' — whose energy and thirst for innovation keep us moving forward. And finally, our youngest generation — Angelique, Chris and Ryan — for their ability to question everything and challenge us to see things differently. By naming a few, many go unnamed. Yet each member has been essential to BAAT's success, as together we have achieved more than a few could have done on their own.

This milestone marks our past and also the future, as we move forward within the GBA Group. A significant and welcome step that prepares us for the next 25 years of innovation, benefit and growth!

Arthur Aalsma

Tackling every challenge and mastering it all

"WE DEVELOP ANYTHING YOU CAN ATTACH TO THE MUSCULOSKELETAL SYSTEM", is how R&D Director Arthur describes BAAT Medical's mission. "Implants for tendon repair, fracture management, joint replacement—you name it. And, of course, the instruments that go with them. While we focus on spine, trauma and orthopedics, over the years, we've also ventured into cardiovascular surgery, diabetes care, pain treatment, and active implants." BAAT laid its foundation for this range of expertise in the late 1990s, with Arthur working on an Intramedullary Leg Lengthening Device for his PhD and Gert developing an orthosis for children with scoliosis. "I was about six months ahead of Arthur", Gert recalls, "but by then, we'd already decided to start a company together." And so, in 1999, BAAT Medical was born. Through distributor SOMAS, whom Gert had known since his doctoral research, their first project was a scoliosis orthosis, followed soon by an orthotic hinge project for Basko Healthcare.

For the past 25 years, Gert Nijenbanning and Arthur Aalsma have led BAAT Medical, a company they co-founded back in their days as PhD students at TU Twente. Their friendship, which began during those early years, remains as strong as ever. "It always just worked well", reflects Managing Director Gert. "We're different personalities, but we know what we have in common. We never argue—though we certainly have our discussions." This dynamic hasn't changed, even as BAAT has grown to nearly forty-five employees. Along the way, Gert and Arthur have embraced roles that suit their individual strengths.

WITH THESE PROJECTS UNDERWAY, BAAT MEDICAL WAS OFF TO A RUNNING START. "For both of us, doing something that improves people's lives is what matters", Arthur notes, "hence our companies' name, which means benefit in Dutch." Their first projects centered on orthosis but soon also moved to implants. The spine became an area of expertise. However, they progressed and soon received requests to work on total knee implants or cardiovascular implants. "We quickly decided we wanted to tackle everything and learn all there was to know—about implants, materials, designs, clinical data, the market, legislation, regulatory affairs, and testing", Gert says. "All of it, so we could fully support our customers and relieve them of any burden during the process."

This approach required many hours of extra work. "Those are hours you can't bill customers for", Gert adds. "As a result, the first few years weren't exactly lucrative, but they gave us a solid foundation." BAAT grew gradually, averaging one new employee each year. Their first hires, Allard and Huub, came from companies that had supplied BAAT with products. "We didn't actively recruit them", Arthur explains. "They simply found what we were doing more interesting."

AS BAAT'S EXPERTISE GREW, SO DID ITS REPUTATION. Each project brought new skills, and each new hire added knowledge. The team stayed abreast of developments in medical science. "We looked into 3D implant printing early on", Arthur says. "We approached clients who had no idea that was even possible." This commitment to staying on the cutting edge has always been central to BAAT's mission: to provide clients with the best advice and, ideally, give them a market advantage.

Today, BAAT employs nearly 45 people and handles around 10 to 12 projects at any given time. "Since 2012, we've taken a more strategic view of our company", Gert explains, "considering what we want and how we can lead from that position. We've grown faster as a result." Arthur laughs: "We've always worked hard as a team, but sometimes it felt like we were tinkering in those early days. The 2008 economic crisis and our responsibility to our employees made us focus more on structured operations."

AS BAAT GREW, GERT AND ARTHUR BEGAN TO TAKE ON DIFFERENT RESPONSIBILITIES. "As Managing Director, I now focus more on new clients, assignments, and project setup. That suits me because, although I completed all technical training up to a PhD, I don't consider myself a true tech guy—unlike Arthur", Gert says. This difference is evident in their hobbies: Gert once considered a career in music as a trombonist – which he still plays in various jazz orchestras – while Arthur's engineering interests extend to tinkering with motorcycles. "Inventing is close to my heart", Arthur says, "so it took me a while to figure out

Growing Pains

"At one point, we started recruiting employees from abroad without planning where they'd live. We quickly arranged a holiday home for them. We're pretty good at solving problems on the fly."

Arthur Aalsma

"The first few years weren't exactly lucrative, but they gave us a solid foundation"

whether I would enjoy building and managing a team. Now, I'm comfortable with it."

In a specialized field like theirs, human resource management is vital. New hires get ample time to find their footing. "Our selection process became stricter, both during applications and in the evaluation of the first year", Arthur explains. "It takes at least two years for someone to reach full capacity here. So we carefully consider if each person can contribute to the team long-term." But they also encourage initiative. "We value employees' self-assertiveness and make sure they don't lose confidence by hitting a dead end."

MAINTAINING AND EXPANDING THEIR COLLECTIVE KNOWLEDGE IS ANOTHER KEY PRIORITY. "Every employee is required to dedicate three weeks each year to their own development", Gert says. This is managed through personal development plans, but BAAT has recently adopted a more structured approach. "Our company has experts in numerous areas - technology, legislation, regulatory affairs, risk management, and medical products", Gert continues. "We don't want to lose that knowledge if someone leaves or is absent. This is why Arthur implemented our Subject Matter Experts."

This system allows employees to stay versatile while also specializing in a particular field. "They're encouraged to invest time and resources—online seminars, trade fairs, publications, short courses abroad, all to deepen their expertise, with which they then educate the rest of the team." The ultimate goal is that the team can handle 50% of issues while the experts take on the rest. "We're even taking this further by setting up an e-learning platform and establishing the BAAT Academy", Arthur adds proudly.

IN 2017, STRICTER REGULATIONS ON MEDICAL DEVICES FOLLOWED SEVERAL IMPLANT SCANDALS IN EUROPE, particularly with dangerous breast implants and pelvic floor mesh. "Due to several reasons, the new regulations were postponed until 2021, but changes were necessary", Arthur says. "Although many issues arose from ignoring previous laws, the new regulations aim for zero risk, which complicates innovation." Gert notes that the increased compliance burden often makes it financially challenging for companies to bring new products to market, "especially for small firms with single products." Many of BAAT's customers now turn to the U.S., where the market-entry process is more transparent and often faster for lower risk developments. "Europe may take another ten years to strike the right balance between safety and innovation", Gert predicts.

WITH THIS SHIFT, BAAT IS FOLLOWING ITS CUSTOMERS WESTWARD ACROSS THE OCEAN while also exploring new regions like Africa, the

“We’ve always worked hard, but sometimes it felt like we were tinkering”

“We value employees’ self-assertiveness and make sure they don’t lose confidence by hitting a dead end”

Middle East, Indonesia and India. “Those are large, emerging markets”, Gert notes. “We can offer state-of-the-art products and manufacture locally for the local market.” Regulatory approvals in the U.S. help BAAT gain acceptance in these regions as well, simplifying entry into new markets.

Besides orientation to other country markets (Arthur: “Where’s that one customer in Hawaii? I haven’t been there yet!”), Gert looks to expand BAAT’s specialties and sees opportunities to assist clients in more focused ways. “While we still enjoy A-to-Z projects, we’re also happy to join a project at any stage, from sterile packaging to feasibility studies”, he says. “With 25 years of experience, we’re well-positioned to make an impact.”

THE MEDICAL DEVICE INDUSTRY IS COMPLEX AND INNOVATION IS COSTLY. And while there is a lot of money to be made with innovative products, investor patience is often short. BAAT can quickly assess a project’s feasibility, but knows that outcomes depend on more than expertise. To address these challenges, BAAT made a significant

decision recently: “As a standalone company, we face big financial risks”, Gert explains. “That’s why we’ve joined the GBA Group, an international life sciences service provider. This partnership makes us less vulnerable and allows us to benefit from other companies’ specializations. It will also help us continue to grow and improve.” Arthur agrees, adding: “People sometimes ask, ‘Will BAAT still be BAAT?’ It’s a fair question, but we’ve been evolving for 25 years. This is just the next step, and it won’t be the last. Joining the GBA group will help us professionalize our organization for further growth, give us boots on the ground in Asia and the U.S. and hopefully expand our field of knowledge. The plan is to expand to other markets, both geographically and in the technology field. The challenge is to move forward as a team, encouraging the sprinters and supporting the stragglers in this next step. That shared dedication and consideration for one another is what makes us BAAT.”

1999

TriaC

Gert Nijenbanning

The birth of BAAT

Correction of scoliotic spines

THE TriaC SCOLIOSIS ORTHOSIS WAS THE PRODUCT THAT STARTED IT ALL. Originally developed as part of Gert Nijenbanning's PhD research in Biomechanical Engineering at the University of Twente, this groundbreaking device represented a major shift in scoliosis treatment. Traditionally, scoliosis (curvature of the spine) had been managed with rigid braces designed to prevent further spinal deformation. However, Nijenbanning sought an alternative, a less restrictive solution that would offer greater comfort to patients. "That became the TriaC", says Nijenbanning, now managing director of BAAT Medical. "It's a flexible brace that gradually reduces the curve by applying continuous pressure."

The research results were promising from the start. "Looking back, it's hard to believe that we could test such a prototype on patients back then", Nijenbanning reflects. "By the end of my PhD program, five people were already using the TriaC." This innovative brace significantly reduced scoliotic curvature while providing more comfort than rigid braces. "The test group was too small to make definitive scientific claims, but the preliminary results were encouraging enough to keep developing it after my PhD", Nijenbanning explains.

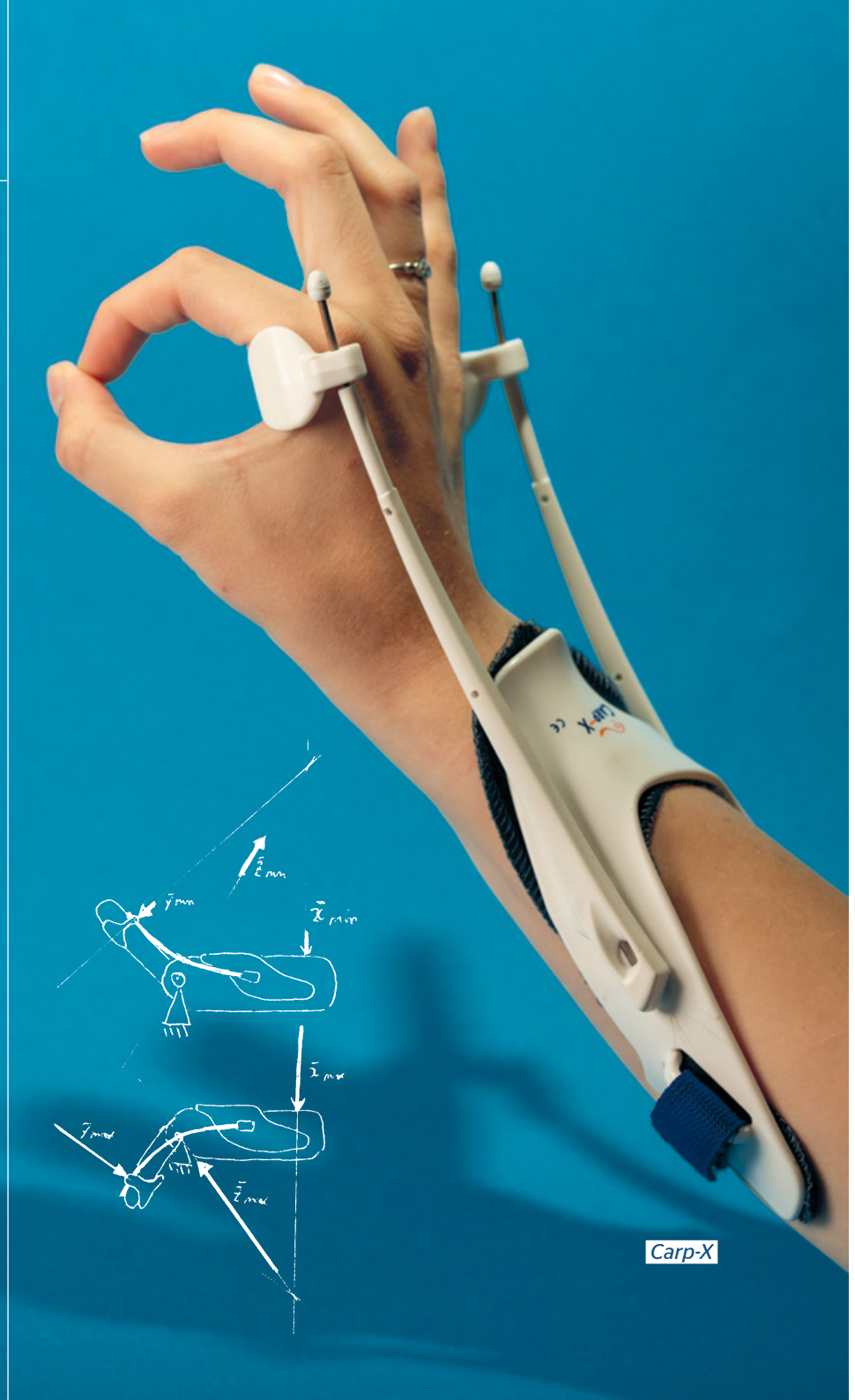
Product: ***TriaC***
Customer: ***SOMAS orthopedie B.V., Sint Anthonis (NL)***
Part of the body: ***Spine***
Start: ***1999***
Development: ***3 years***

"The TriaC offers similar results to other braces while greatly enhancing comfort with its flexible design"

"I wanted to explore if I could bring the TriaC to market and reach more people than just those initial test patients." This ambition led him and fellow PhD student Arthur Aalsma to establish BAAT with a mission to develop patient-centered medical devices.

IT WASN'T LONG BEFORE NIJENBANNING CONNECTED WITH SOMAS ORTHOPEDIE B.V., a Dutch distributor interested in launching its own products. During this time, he frequently met with SOMAS sales manager Harmen Berends, who recalls: "Gert had just come out of university, he was very much still a student. I remember when we presented the TriaC to a group of investors. He wore a suit, probably for the first time, and commented, 'This is a very different world than what I'm used to'", Berends says with a smile. "Gert wasn't concerned with money or marketing; he just wanted to create great products." Although, according to Berends, Nijenbanning has always remained the same amiable and authentic person, he has seen the BAAT founder grow. "Together with Arthur, he's built a remarkable company. He's mastered the business side too, but his passion for product development is still the driving force, alongside his commitment to improving patients' lives and comfort. That enthusiasm and idealism have been the basis of BAAT's success for 25 years."

The TriaC has been available for over 20 years, though it didn't become the new global standard Nijenbanning envisioned. "We quickly realized that the orthosis worked so differently from



conventional methods that it couldn't dominate the market as we'd hoped", he explains. "Traditional braces provide an immediate, visible correction, while the TriaC takes a more gradual approach. Because of this, it takes longer to see visible results, and unfortunately, you don't get that time from the market." Despite this, the TriaC remains an effective scoliosis solution, offering similar results to other braces while greatly enhancing comfort with its flexible design. Nijenbanning: "The TriaC is still on the market and has carved out its place, and I'm very proud of that."

More Product Development

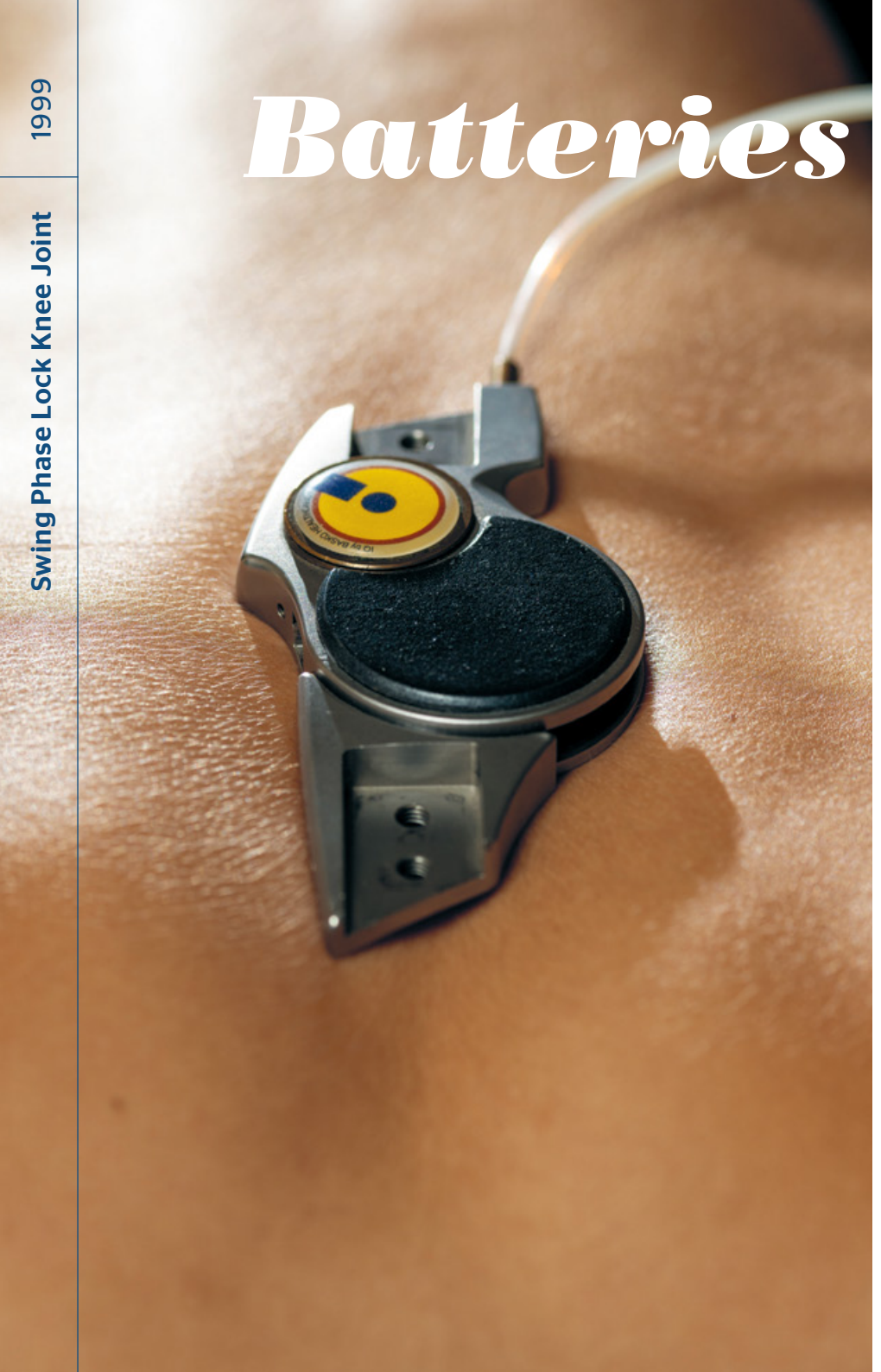
The TriaC is just one of several products BAAT has developed in partnership with SOMAS and later with Össur. Among these is the Carp-X, a dynamic brace for treating tennis elbow. "Most braces simply apply pressure to the painful area, which essentially just shifts the pain," explains Harmen Berends. "The Carp-X tightens the muscles at the bottom while relaxing those at the top, which helps alleviate the pain." However, Nijenbanning considers their most successful collaboration to be the HipTric, an orthosis designed to prevent hip dislocation. Developed with SOMAS and marketed by Össur, the HipTrick was born from a simple idea: adapting the TriaC's flexible design for hip support. "We essentially lowered the TriaC concept to fit the hip, creating an orthosis that has since been very well-received and is still available today", says Nijenbanning.

What is typically BAAT?

Ryan D'Souza:

"The structure at BAAT is really flat. Everybody works on equal terms and takes responsibility. It doesn't feel like somebody is micromanaging you. We all have the same values and motivation, which is—to do what's best for our clients."

"BAAT is a close-knit group. People do care about you as a person. I feel I can trust and depend on my colleagues, and they can depend on me. When you trust that your team has your back, you have the confidence to push boundaries. And that's what's needed to be innovative."



Batteries not included

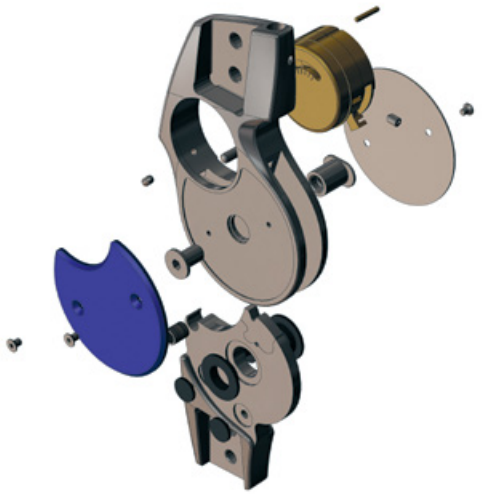
Walking safely with an orthotic knee joint

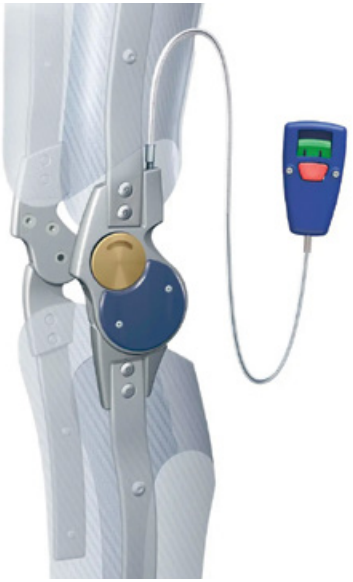
"HUUB, TAKE A LOOK AT THIS. *Walking with this knee joint keeps me from falling." More than twenty years ago, Huub ter Braak, a project engineer at BAAT Medical, listened intently to his uncle, watching as he demonstrated the SPL (Swing Phase Lock) knee joint. Huub immediately recognized it because it was a product he'd helped develop, and he shared his uncle's enthusiasm.*

"This joint has been in production with Basko Health Care since 2002, sold across almost all of Western Europe and the USA for over two decades. That's truly exceptional." The SPL knee joint marked a major milestone for BAAT, a startup company at the time, putting them on the map. Needless to say, Huub eventually took his uncle to Hengelo to show him where his knee joint had been created.

BAAT developed the joint based on Basko Healthcare's initial concept, explains Director Harold Jörning. "A colleague had been wrestling with the idea of automatic locking and unlocking for some time. We brought the concept to BAAT, and Director and Engineer Gert Nijenbanning discovered the missing piece of the puzzle in the form of a weighted rubber duck", he says with a smile. "I already knew Gert from previous projects, and he more than lived up to my expectations of him and of BAAT. Developing this kind of orthosis always involves a bit of trial and error. The mechanical part can be tested on a setup and may work well from an engineering perspective, but it

Product: ***Swing Phase Lock Knee Joint***
Customer: ***Basko Healthcare, Zaandam (NL)***
Part of the body: ***Knee***
Start: ***1999***
Development: ***2 years***





also has to fit seamlessly into users' everyday lives. For instance, many users with this kind of orthosis find climbing stairs easy, which still surprises me, but they sometimes struggle with slopes. The SPL joint can be adjusted to accommodate these differences."

THE JOINT PRIMARILY SERVES PATIENTS WITH KNEE INSTABILITY. The moment they start walking, they can't lock their knee due to insufficient strength or muscle control, causing them to collapse. Ter Braak says the SPL joint prevents this: "When you initiate a walking motion and swing your lower leg forward to the furthest point, the joint automatically locks. When you place your foot back down, your knee is securely locked so you won't collapse." After developing the prototype, Jörning and Nijenbanning met at a hotel in Amsterdam to test it out. "In the car park, Gert walked up to me. 'Do you notice anything different about me?', he asked from a distance. 'No, why?', I replied. 'I'm wearing it!', Gert exclaimed enthusiastically. "The fact that a 'user' could walk around unobtrusively with the joint was what truly completed the project for me."

Over 20 years later, the SPL joint has secured a significant place among clinical options for knee care, says Jörning. "It's certainly an innovative product", agrees Ter Braak. "With other joints, for example, you have to put your heel down first, and only then does your knee lock. Many patients tend to find that unnatural and annoying." The SPL joint, however, operates entirely autonomously. It doesn't require batteries. Ter Braak notes: "Some other joints function similarly but rely on batteries. If the batteries die, users can suddenly collapse. With the SPL, you could stand at a bar for hours without any risk. That's what makes this joint feel so safe."


Harold Jörning

2000

S² Micro-Stapler

Anastomosis by staples

Automated suturing of blood vessels

FEW PROCEDURES ARE MORE INVASIVE THAN BYPASS SURGERY, where a heart surgeon reroutes blood flow around a blocked coronary artery by connecting it to another blood vessel. Traditionally, this involves manually suturing vessels together with a needle and thread, which requires opening the chest, a strenuous surgical procedure. In addition to health risks, the surgery also requires extensive recovery time. Twenty-five years ago, heart surgeon Willem Suyker believed there had to be an easier way. Along with his tech-savvy brother Paul, he founded the company iiTech and developed the S² Micro-Stapler, which became the subject of Willem's thesis. The instrument functionality based on the common stapler was intended to connect blood vessels in a less invasive and more automated way, using a one-shot connector instead of numerous sutures.

The Suyker brothers knocked on BAAT's door early in their development process. "We wanted to patent the micro-stapler but had no idea how to go about it", Willem recalls. "As a surgeon and a mechanical engineer, we weren't familiar with that part of the process. A colleague in Zwolle

Product: ***S² Micro-Stapler***
Customer: ***iiTech (UMC Utrecht), Amsterdam (NL)***
Part of the body: ***Heart***
Start: ***2000***
Development: ***3 years***


Paul Suyker

recommended BAAT, and Gert helped us secure funding for a feasibility study. That was the beginning of our adventure."

BAAT STAYED INVOLVED IN THE PROJECT EVEN AFTER THE INITIAL STAGE. "I built the original prototype myself, at a 2:1 scale", Paul says. "BAAT then made a professional version at the same scale, which we tested in Eindhoven. Willem wanted to ensure the first connection was watertight, but he applied too much pressure in his excitement, causing the prototype to break apart. That marked the end of our first test—it was clear we needed force feedback in the next design." The incident underscored the challenges of using automated anastomosis technology for coronary artery connections. "These vessels are only 1.5 to 2 mm wide, so the device had to be extremely small", Willem explains. "And that was just the 2:1 model. Later, BAAT helped us create an even smaller true-to-size model. It was a highly specialized job, one that was handled excellently."

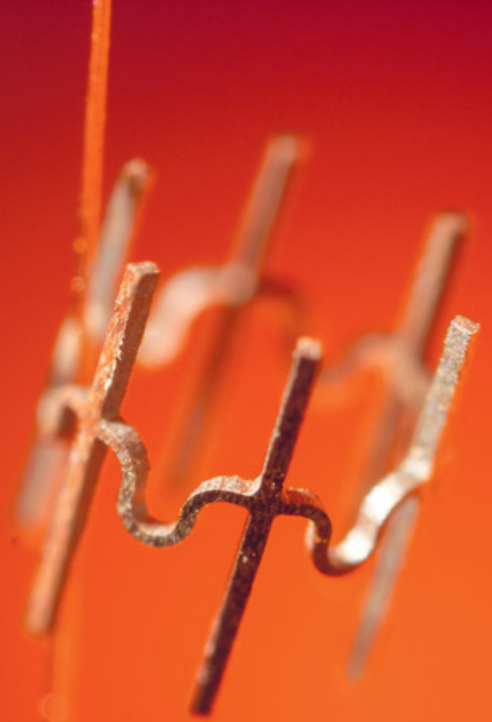
The professor of cardiothoracic surgery fondly recalls the collaboration: "Gert used to travel to my house in Zwolle on weekends to deliver parts. BAAT's service was first-class even then."

BAAT's R&D Director, Arthur Aalsma, occasionally visited Paul as well. "I clearly remember my first visit", he says. "Both brothers are distinguished people, and Paul lived in a beautiful townhouse on a canal in Amsterdam. So, I expected a formal meeting in a refined setting. Instead, I found that Paul had a full workstation in his house, including a lathe, all on the third floor. One of those things easily weighs 400 kilos; I have no idea how he got it up there."

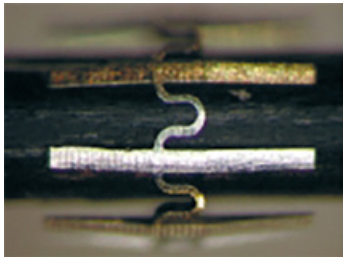
TO AALSMA, THIS CAPTURES THE ENTHUSIASM AND INGENUITY OF THE SUYKER BROTHERS. "They're incredibly knowledgeable in their fields. When working with other companies, we usually interact at the marketing level, and they leave the technical side to us. But with Willem and Paul, we were constantly clinically and technically challenged. Our discussions were always substantive; sometimes they brought up things we hadn't considered. We pushed each other to achieve even better results."

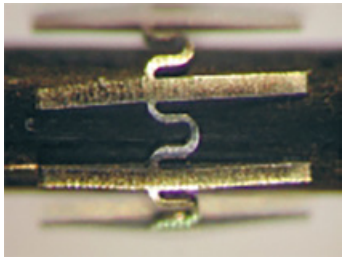
While the American multinational Johnson & Johnson initially invested in the micro-stapler, a change of focus within the company halted the project. "It was unfortunate because BAAT and the U.S. team had already developed a fully validated production model", Willem says. However, the partnership with BAAT continued. "For several years, we worked on an angled stapler to connect the outflow conduit of cardiac assist devices to the aorta", Aalsma explains. "Then, they started their current project, essentially a further development of the micro-stapler."

AALSMA IS REFERRING TO THE OCTOCON. The Suyker brothers couldn't let go of the idea of the micro-stapler, so they eventually founded the company OctoVascular, where they're now working

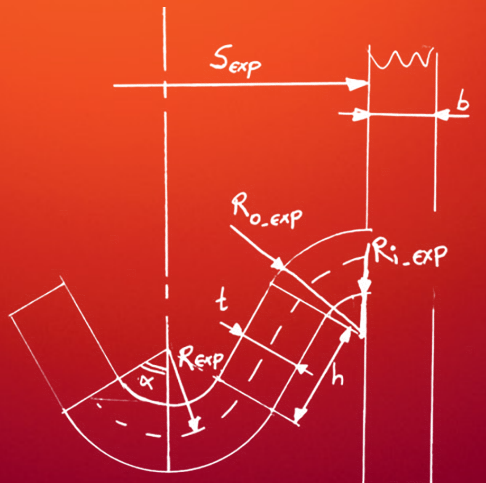


Arthur Aalsma





“The discussions were always content-related and sometimes they came up with something we hadn’t thought of. This way, we pushed each other to get to even better results”



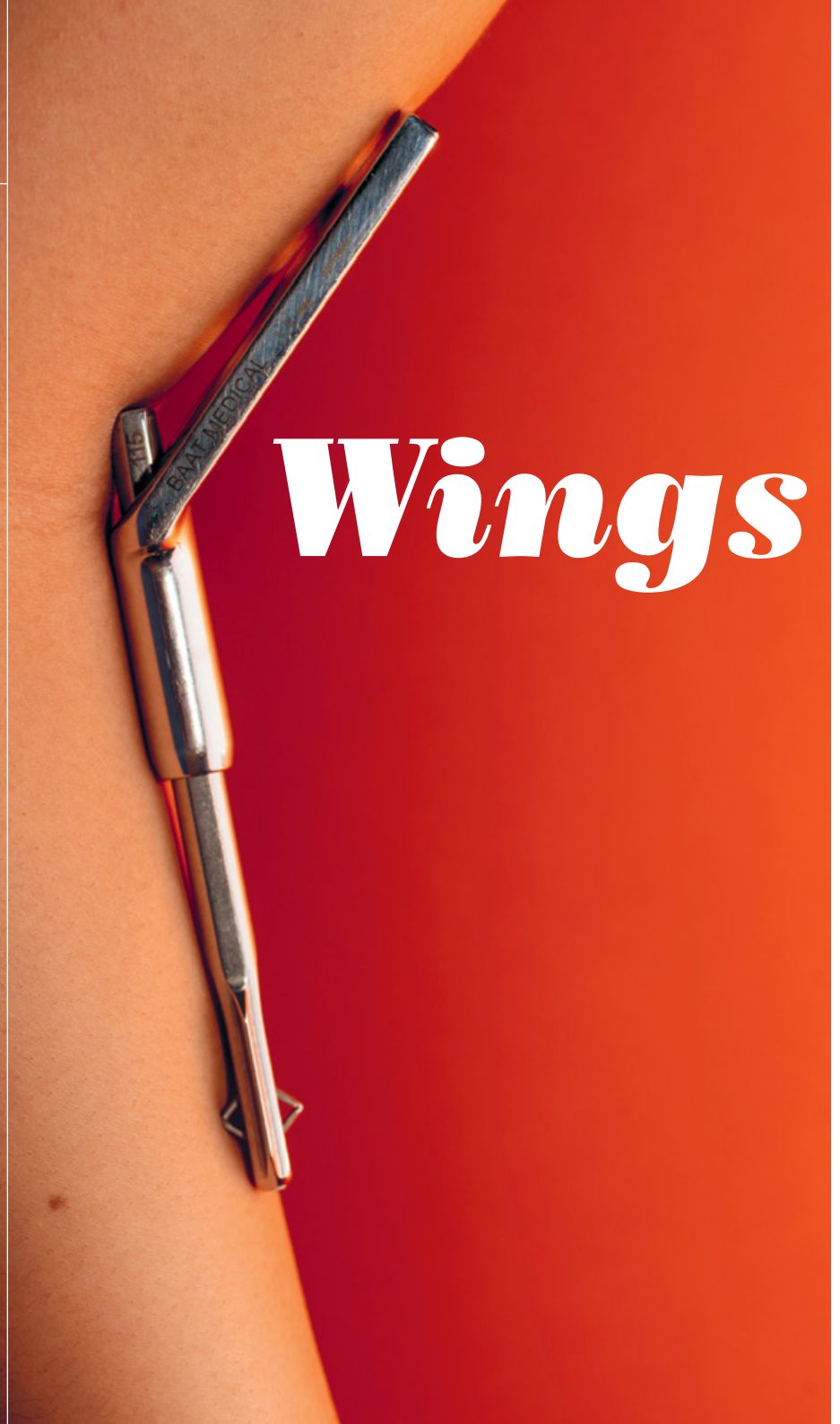
on an improved version of the S². The idea is for the surgeon to attach tiny rings with staples to the donor vessel and coronary artery, then snap them together. “The technology is even more advanced now. We’ve gained new insights over the years, and engineering keeps evolving. For example, consider the possibilities of 3D printing”, Paul says. Willem shares the enthusiasm: “The Octocon is more user-friendly, and the technology is now so reliable that the success rate is higher than ever. We recently conducted a successful test with robots in America, and I’ll soon present the device at a major surgical conference. Although BAAT isn’t directly involved with the Octocon, the product is still based on the staple technology we originally developed together”, Paul adds proudly.

What is typically BAAT?

Martijn Heikens:

"Gert and Arthur started this company right after their PhD. They're two pragmatic, no-nonsense engineers who are eager to learn, and self-taught entrepreneurs who are genuinely invested in the business. That energy radiates throughout the organization, making the people here open, honest, and authentic. There are no politics, no hidden agendas, and no rigid rules about what you can or can't do."

"Sometimes potential clients will test our professionalism by asking a few specific questions upfront. By providing them with expert answers, the trust is established right from the beginning. From then on, they often give us full creative freedom, so to speak, because they know we have things under control."



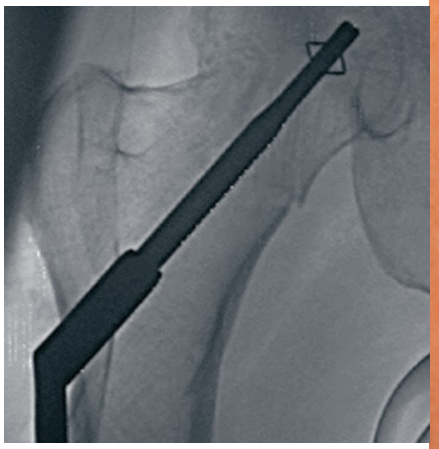
Fixation system for hip fractures

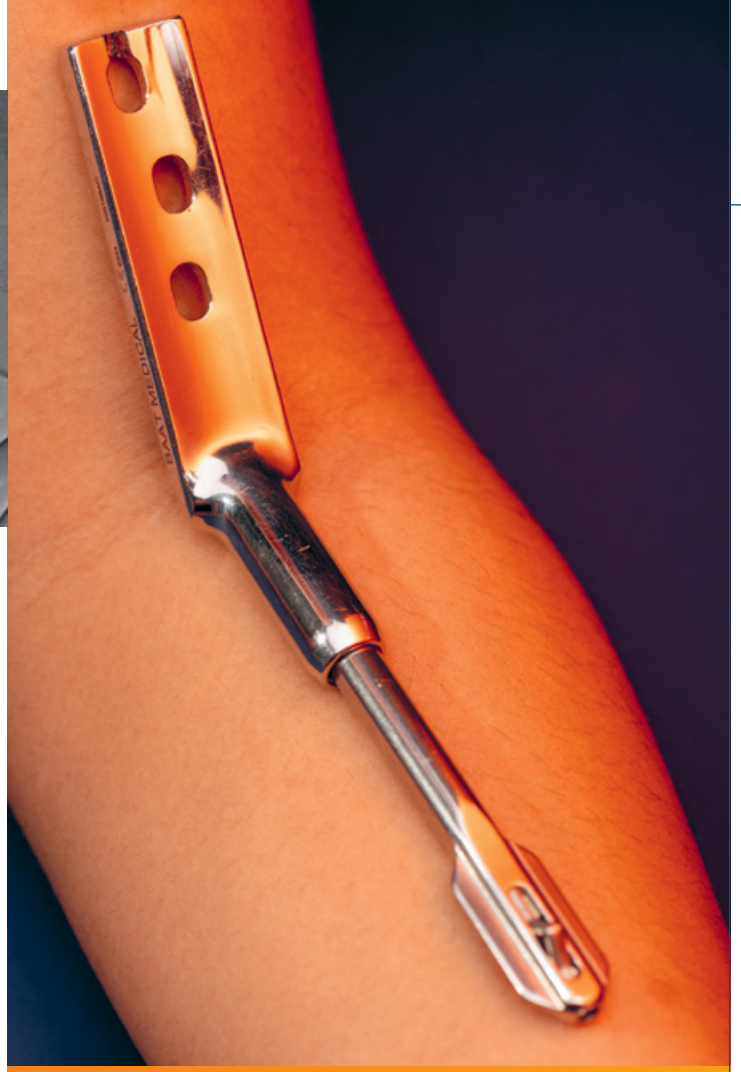
Wings for stability

THE GANNET HIP IMPLANT OFFERS A RELIABLE AND RAPID PATH TO HEALING HIP FRACTURES. A pin inserted into the femoral head through a minimally invasive procedure, this innovative device uses two expanding ‘wings’ to achieve stable anchorage. Additional screws secure a plate to the femur, holding the fractured parts firmly together. With its design allowing nearly unrestricted mobility, patients can get back on their feet quickly post-surgery.

The GANNET’s story began around 25 years ago when trauma surgeon Ariaan van Walsum grew increasingly concerned about the complications he observed in hip fracture treatments. A common issue was that the femoral head would lose vitality, often requiring a total hip replacement. At the time, Edsko Hekman of the University of Twente was researching similar procedures and introduced Van Walsum

Product: ***GANNET***
Customer: ***GANNET B.V., Hengelo (NL)***
Part of the body: ***Hip***
Start: ***2002***
Development: ***Next Generation ongoing***





to BAAT's Gert Nijenbanning and Arthur Aalsma. The combined vision of Van Walsum and BAAT's engineering expertise led to the creation of the GANNET.

"THIS WAS ONLY MY SECOND MAJOR PROJECT WITH BAAT", recalls experienced engineer Huub ter Braak, reflecting on the GANNET's development in 2002. "There were just four of us at BAAT back then. I remember Van Walsum frequently joining our consultations. The design involved a lot of innovation, so we constantly tested, adjusted, tried things out on the machine, and reworked them. It was a process of three steps forward and two back until we had perfected it."

Even when the GANNET was ready, some challenges remained. "To market a product in Europe and the U.S., CE and FDA approvals are essential", explains Ter Braak. "This can be tough, as you need to prove that your product is as effective as existing solutions. Since the GANNET was so different from current implants, this was no small feat." The GANNET ultimately earned the CE mark for use in Europe, and now work is underway

Streamlined Seabird

The concept and name for the GANNET originated from trauma surgeon Ariaan van Walsum, who passed away in 2023. Besides being a driven trauma surgeon, he was also a passionate sailor. During one of his journeys, Van Walsum was inspired by the gannet bird, which folds its wings tightly to dive into the water - a movement reminiscent of the implant's fold-in and fold-out mechanism.

“It was a process of three steps forward and two back until we had perfected it”

Huub ter Braak

on version 2.0 to achieve FDA approval for the American market. “This next iteration considers factors like the higher average body weight in the U.S.”, Ter Braak adds.

THE DEVELOPMENT AND COMMERCIALIZATION OF THE GANNET are led by CEO Peter Arensman, who has been steering the project for the past year and a half. However, his involvement dates back even further. “I’ve long invested in products I believe in, which led me to support the GANNET ten years ago”, he explains. “While BAAT and the distributor BDH handle the operational aspects, I’m committed to overseeing the operation and securing FDA approval for the U.S. I’m not one to give up easily and will do whatever it takes to see this through.”

Peter Arensman

“I’ve long invested in products I believe in, which led me to support the GANNET ten years ago”

Investment Recouped

In his teens, a motorcycle accident left Peter Arensman with a shattered leg. “I thought I’d just have to live with it until I was at a shareholder meeting and Adriaan van Walsum, inventor of the GANNET, suggested I get surgery”, he recalls. “He saw my limp and said, ‘Drop your pants.’ So, there I was at the meeting, pants down to my ankles! After examining me, he assured me that surgery had a high chance of success, and I went through with it eight years ago. Since then, I’ve had a straight leg again and am far more mobile. So, personally, my investment in GANNET has already paid off.”

Get up, stand up

Product: ***Fall Simulator***
Customer: ***Bas Bloem, Radboudumc, Nijmegen (NL)***
Part of the body: ***Full body***
Start: ***2006***
Development: ***4 years***

Identifying causes of balance loss in high-risk patients

WHAT HAPPENS TO YOUR MUSCLES WHEN YOU LOSE YOUR BALANCE? How do you move when you're at risk of falling? And how do age and neurological disorders like Parkinson's and Alzheimer's impact your stability? In 2006, Professor Bas Bloem, a neurologist at Radboud University Medical Center in Nijmegen, approached BAAT with questions like these. Working with the Rehabilitation Department, he sought to develop a movement platform to help identify the causes of balance loss in patients with neurological conditions, the elderly, and people with physical disabilities. Their research aimed to create strategies and training programs that reduce the risk of falls—and thus, injuries and hospitalizations. By preventing falls, they hoped to alleviate both patient suffering and medical costs, which run into hundreds of millions annually.

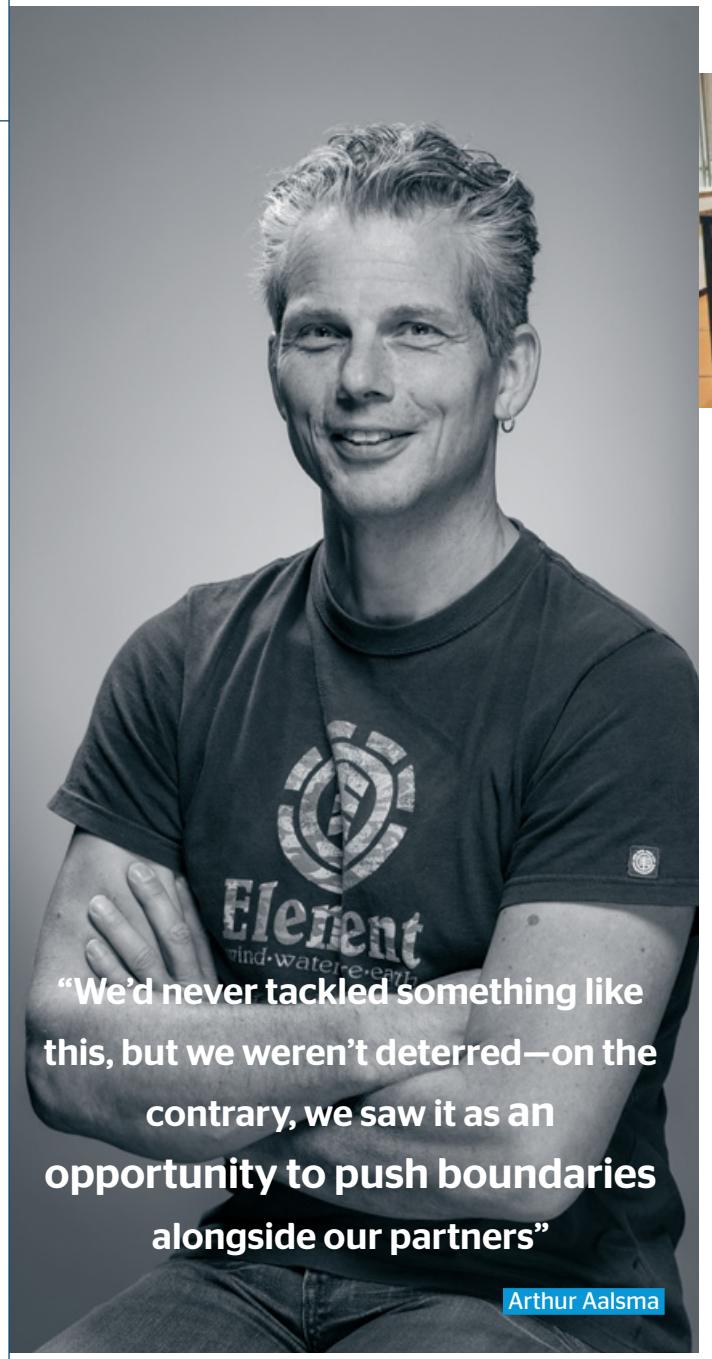
It was an ambitious and challenging project, and R&D Director Arthur Aalsma reflects on it with pride. "Bas laid out his vision: a platform that could move and tilt in every direction and accommodate individuals standing and in a wheelchair, even allowing short walking movements forward or backward", Aalsma says. "The platform needed to detect the force and direction of each movement as people balanced on it, making it a complex design and engineering feat. We'd never tackled something like this, but we weren't deterred—on the contrary, we saw it as an opportunity to push boundaries alongside our partners."

THROUGHOUT THE DEVELOPMENT, BAAT CONSULTED CLOSELY WITH THE RESEARCHERS at Radboud's Rehabilitation Department. "Our biggest challenge was translating the clinical requirements into a viable electro-mechanical design", Aalsma explains. "We worked closely with the Radboud team to set realistic expectations and find creative solutions. That collaborative process is typical for us: if a concept isn't initially feasible, we look for alternatives together. Often, this can lead to solutions the customer hadn't anticipated but that actually enhance the project's original goals."

Professor Bloem shared similar excitement: "With this platform, we are exploring the impact of neurological conditions,

Bas Bloem

Professor Bas Bloem, the initiator of the fall simulator, is widely recognized as a leading Parkinson's disease researcher. A member of the Royal Netherlands Academy of Arts and Sciences (KNAW) since 2020, Bloem received the prestigious NWO-Stevin Prize in 2022, one of Dutch science's highest honors. As co-founder of ParkinsonNet, a network of healthcare providers, Bloem was also awarded a Royal distinction in April 2022.



“We’d never tackled something like this, but we weren’t deterred—on the contrary, we saw it as an opportunity to push boundaries alongside our partners”

Arthur Aalsma

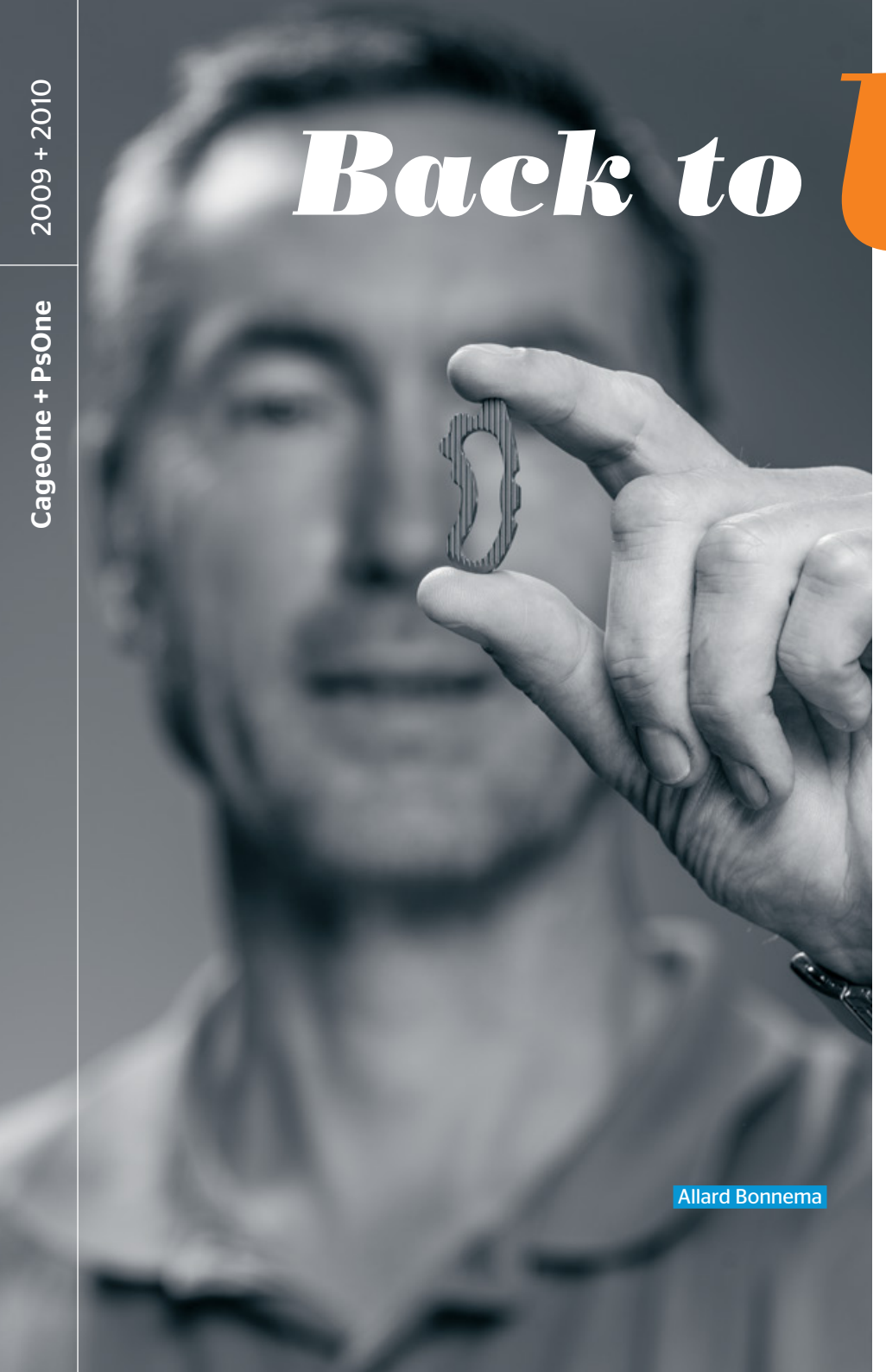
In a Harness

The platform challenges participants’ balance with unexpected movements, but safety comes first. All participants wear a harness attached to an overhead cable to prevent injury.

like Parkinson’s or strokes, on balance and falls. We’re also studying how aging affects stability. From these insights, we hope to create new training programs to improve body balance and prevent falls.”

BAAT DEVELOPED THE EXTENSIVE PLATFORM AND SOFTWARE, PARTNERING WITH AN EXTERNAL TEAM FOR THE MOTOR DESIGN.
Four years after the initial discussions with Bloem, the innovative fall simulator was ready, and Radboud put it to work for rehabilitation, research, and training. “It wasn’t the first motion platform in existence, but it was by far the most advanced”, Aalsma notes. “Earlier platforms were usually adaptations of flight simulators. Ours is far larger and much more versatile, enabling a wider range of scenarios to be tested.”

The platform was initially assembled in a factory hall to ensure everything worked seamlessly before moving it to Radboud. “We had to make sure everything was perfect because once installed at the university, we couldn’t make major changes”, Aalsma recalls. The final setup took slightly longer than expected, leading to an amusing incident. “We were finishing up late one night, but since security was aware of our work, they assured us we could leave once done. During adjustments, we used a grinder to trim a piece that didn’t quite fit. That worked, but a moment later, we suddenly heard a commotion, and when we opened the door, we were surprised to see the entire hallway filled with firefighters. Several fire trucks and a ladder truck had arrived because the smoke from the grinder had activated the university’s fire alarm. The silent alarm had triggered the fire department due to the smoke, but we had no idea. The firefighters weren’t thrilled about the false alarm, and it certainly wasn’t the last we heard of it.”


Allard Bonnema

Back to basics

Simplification of surgical kit for Interbody Fusion Devices

THIS PROJECT BEGAN, AS MANY DO, WITH A MEETING AT A CONFERENCE. At the German Congress of Orthopedics and Traumatology (DKOU) in Berlin, BAAT met Peter Kröner, owner of the medical wholesaler Kröner Medizin Technik, which later merged with ASM. Kröner was in contact with two surgeons at the Markgröningen Klinic near Stuttgart, who wanted to simplify the surgical kit for treating Degenerative Disc Disease. Their business plan was simple: a streamlined set would allow quicker surgeries and lower costs. Kröner's design brief to BAAT was direct and to the point: Back to basics.

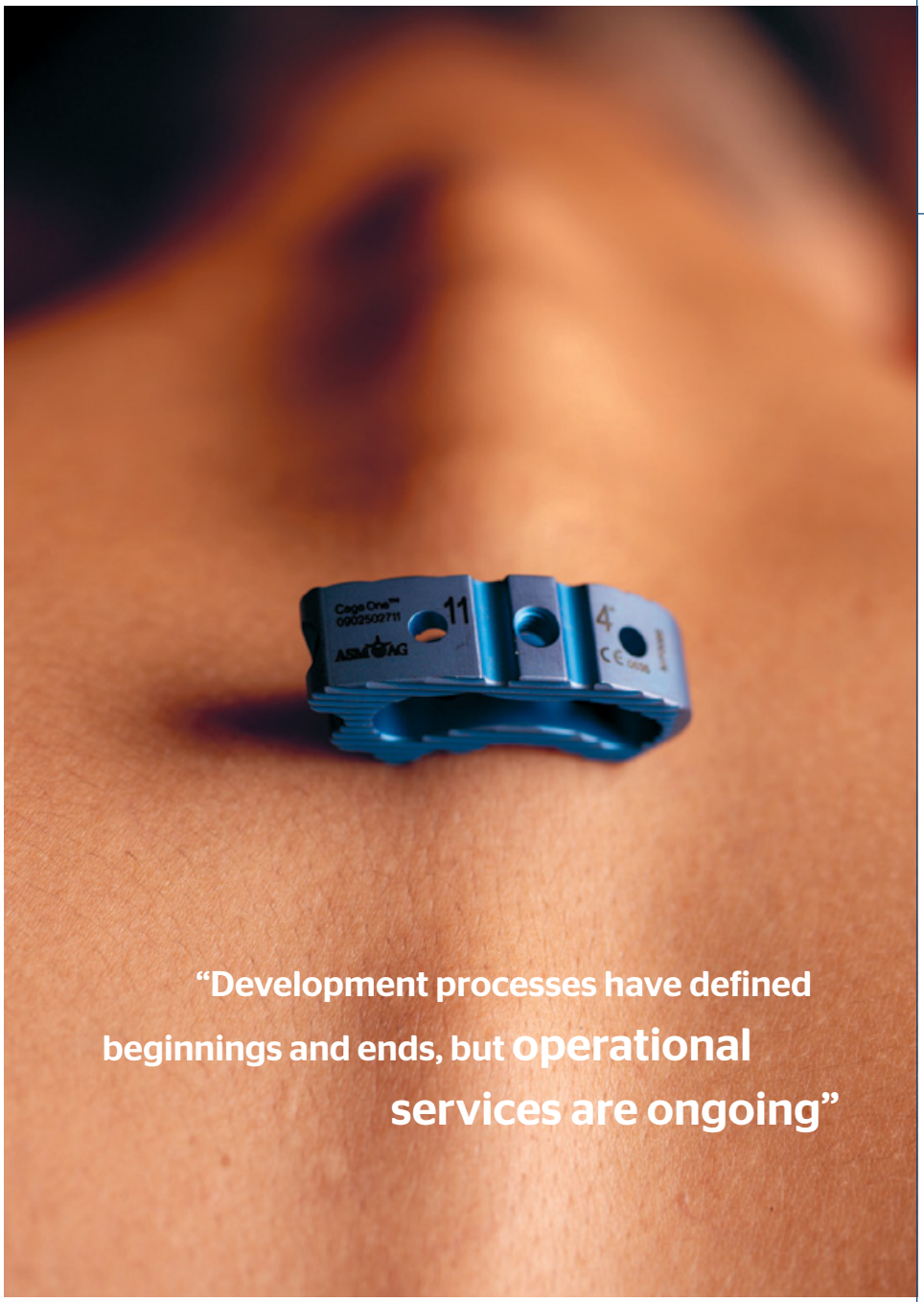
Most major orthopedic manufacturers provide sets to perform this kind of procedure, but these sets consist of two or even more sterilization cassettes of instruments and implants. "We reduced that to one tray, with the bare essentials: an inserter, extractor, and a pair of trial sizers", explains Lead Engineer Allard Bonnema proudly.

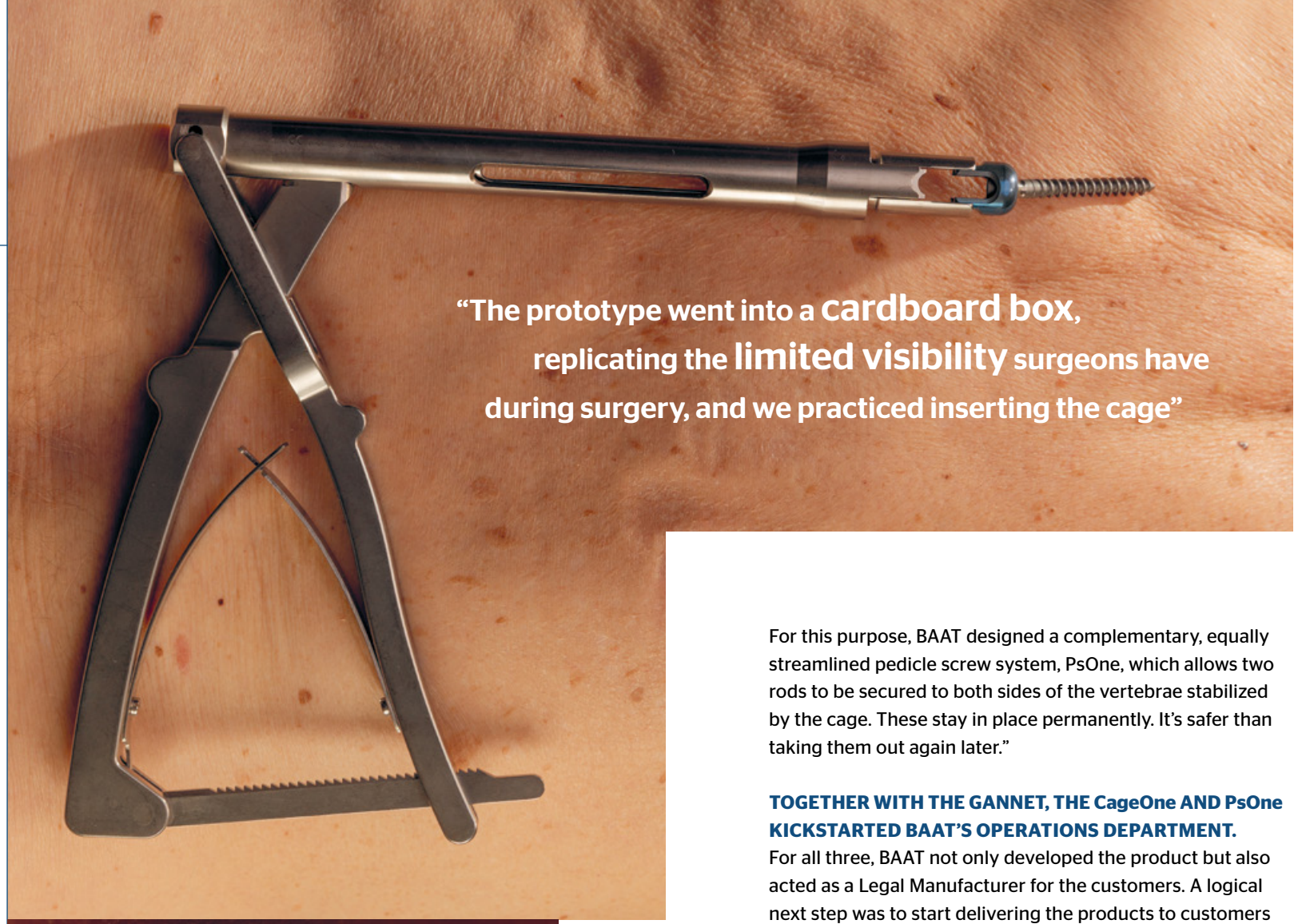
BAAT HAD PRIOR EXPERIENCE DESIGNING AND CE MARKING IMPLANTS. With CageOne, they were able to bring this expertise even further to the market. The project

Products: ***CageOne and PsOne***
Customer: ***Apollo Swiss Medical (ASM), Kreuzlingen (CH)***
Part of the body: ***Back***
Start: ***2009 and 2010***
Development: ***Both within 18 months***

progressed like clockwork, and Bonnema still refers to it when illustrating the importance of continually adjusting design, risk management, and requirements throughout a project. “We wanted fast results. The design brief stated: only what’s absolutely essential to insert a titanium block from all possible access directions. So both straight and angled from behind, from the front, and the side. Within six weeks we had tested the first prototypes in a test set-up of two Perspex plates with a cross-section of a vertebra drawn on them and springs in between to simulate resistance. The prototype went into a cardboard box, replicating the limited visibility surgeons have during surgery, and we practiced inserting the cage. Then, we’d take off the box to see if it worked. By the third attempt, it was a success. We developed that concept into a product within six months.”

It’s common practice to pair an Interbody Fusion Device with a fixation system on the back of the vertebrae. Bonnema explains: “After placing the cage, there’s still some movement, so you want to stabilize the two vertebrae so they can fuse within six weeks.





“The prototype went into a **cardboard box**, replicating the **limited visibility** surgeons have during surgery, and we practiced inserting the cage”

For this purpose, BAAT designed a complementary, equally streamlined pedicle screw system, PsOne, which allows two rods to be secured to both sides of the vertebrae stabilized by the cage. These stay in place permanently. It’s safer than taking them out again later.”

TOGETHER WITH THE GANNET, THE CageOne AND PsOne KICKSTARTED BAAT’S OPERATIONS DEPARTMENT.
For all three, BAAT not only developed the product but also acted as a Legal Manufacturer for the customers. A logical next step was to start delivering the products to customers as well. “Development processes have defined beginnings and ends, but operational services are ongoing. As BAAT’s customer base grew, we needed to free up R&D engineers from operational tasks and set up a dedicated team”, says Bonnema. This led to the start of the Operations department, which now has six team members.

What is typically BAAT?

Odmar Christiaanse:

"We have several clients from Tuttlingen, Germany, which is often referred to as the Medical Silicon Valley of Germany. It's quite a journey, so our in-person meetings often involve long days. As the tradition goes, we usually wrap up these meetings with pizza and beer, but we also make it a point to skip the pizza and enjoy a meal at a 'real' restaurant from time to time."

Adapting to a new method

Repairing collarbone fractures

COLLARBONE FRACTURES ARE COMMON IN CYCLING, MOUNTAIN BIKING AND CONTACT SPORTS LIKE RUGBY. While slings and rest are the most common way of treating a collarbone fracture, some people benefit from surgery. “Surgeons place a metal plate over the fractured collarbone”, explains Maarten Pijper, lead engineer at BAAT Medical. “It works well, but there are drawbacks, like a noticeable scar and a visible bulge or thickening on top of the clavicle.” This thickening can lead to irritation of the skin during daily activities like carrying children or backpacks.

In 2011, surgeon Paul Hoogervorst, then a medical resident in Nijmegen, began looking into better treatments for mid shaft clavicle fractures. His solution? A thin pin that allows some bending and rotation but restricts axial movement of the fractured clavicula securing alignment and length. Professors Albert van Kampen (Orthopedics) and Nico Verdonschot (Biomechanics) at Radboud UMC saw potential and provided a small budget for prototyping. “Verdonschot knew Arthur Aalsma from BAAT, which led us to connect and begin our work”, says Hoogervorst. The pin’s design allows for a smaller incision and removal after recovery is not necessary. It also enables patients to move again quickly and more naturally during recovery, which in turn speeds up the healing of the fracture.

“BAAT WAS STILL RELATIVELY SMALL BACK THEN”, Hoogervorst recalls, “and we set off on a fantastic shared adventure.” Surgeons and BAAT staff

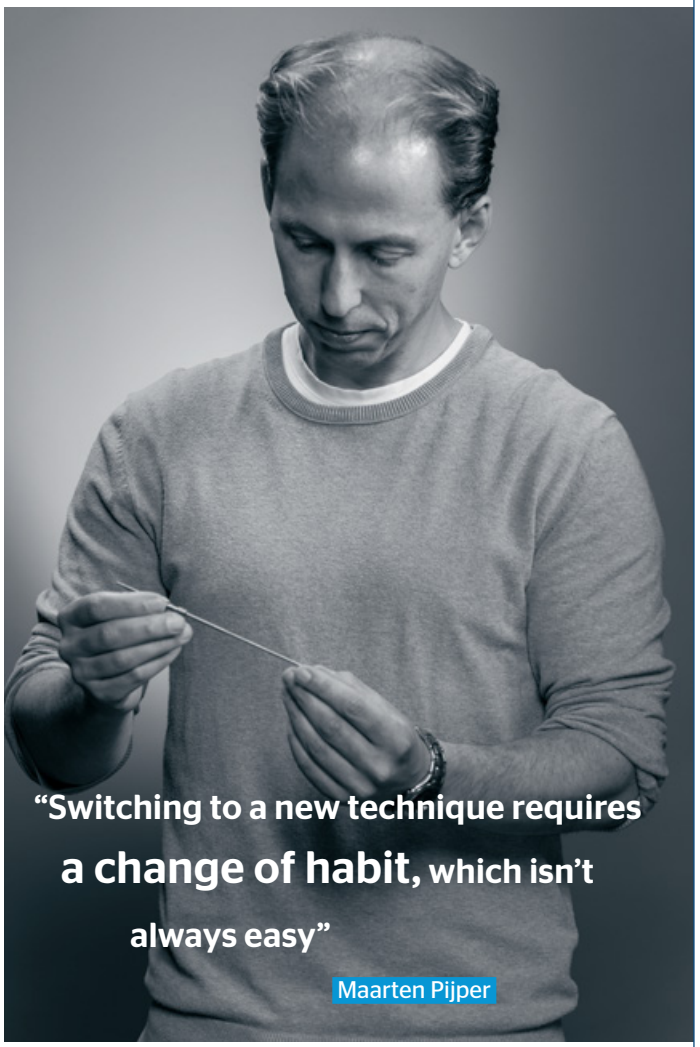
Product: ***Anser Clavicle Pin***
Customer: ***Anser Implants BV, Amsterdam (NL)***
Part of the body: ***Clavicle***
Start: ***2011***
Development: ***2 years, 3 months***

worked closely, performing cadaver tests at Radboud UMC, analyzing results, and refining the design together. “Some surgeons want to tell us how to do our job”, Pijper laughs. “But in this project, we really respected each other’s expertise.” Hoogervorst adds: “I’ll always be grateful for BAAT’s support. They invested time, money, and energy into this. We secured multiple funds and investments for further development and validation.”

Pijper explains how the pin works: “The surgeon drills a small hole on the lateral side of the collarbone, then places the thin flexible pin into the bone, which aligns the broken fragments. The fractured collarbone is secured in length and alignment by adding an end cap to the pin. Because the pin can be cut to the patient specific length, it works for patients of all shapes and heights.” The material had to be strong yet flexible enough to follow the curvature of the clavicle. “We first considered memory metal but ultimately chose titanium, which is widely used and reliable.”

THE ANSER CLAVICLE PIN has since been admitted to the European and American markets. Hoogervorst sums it up: “It took patience, persistence, and sometimes a bit of frustration, but BAAT finally obtained the CE marking for the Anser Clavicle Pin. As one of the first projects - and probably somewhat as a guinea pig - the Clavicle Pin received a 510(k) submission from the FDA to the U.S. market, thanks to its demonstrated safety and effectiveness compared to similar devices. With this momentum, we co-founded Anser Implants, aiming to expand in the U.S., which is our focal point and where I now live.”

THE REAL CHALLENGE FOR THE ANSER PIN, PIJPER BELIEVES, IS THE SHIFT IN PRACTICE. “Surgeons have muscle memory with traditional bone plates—they could almost perform the procedure with their eyes closed. Switching to a new technique requires a change of habit, which isn’t always easy.” Hoogervorst agrees: “Education on a paradigm shift is important and challenging. Luckily the design and implant seems to do exactly as it promises.”



Operations manager Christos Michael:

“Our role is to unburden the customer”

WE MANAGE PRODUCT QUALITY AND SUPPLY CHAIN LOGISTICS FOR OUR CUSTOMERS, including coordinating with suppliers to ensure timely delivery. If there’s a delay or issue, we work directly with the supplier to resolve it. We also ensure that the product is traceable. This means that for each product, we know when, where, and by whom each product was made and to which customer it was delivered.

When products arrive from suppliers, we inspect them for quality. If something’s off, we address it, usually by coordinating with the supplier. Once everything checks out, we send the products to our customers. Our customers don’t see all the work that goes into this process; they simply receive the product, with us taking full responsibility. If anything goes wrong, it’s on us to fix it.

CURRENTLY, WE SUPPORT EIGHT CUSTOMERS, AND THREE MORE ARE UNDERWAY; they are still in development. New customers start with our R&D department, progressing from concept to product. At that point, a validation phase ensures the product is patient-safe and ready for use. Because traceability in production is also

In 2016, BAAT began offering production as a service for its commercial products, extending support to customers beyond the development phase. Former Operations Manager Ward Verschuur established the 'Ops' department eight years ago, and since May 2024, Christos Michael has taken over as its manager. "We supply eight customers worldwide with products that they, in turn, sell to hospitals", he explained.

important in this phase, the production of test samples also goes through Operations. This is often the first time Operations is introduced to a new customer and product.

If the validation tests are successful and the product is approved, the transfer to Operations takes place, and all production orders go through us. Development is done, the customer starts delivering the products to the hospitals, and we handle the supply chain.

OUR ROLE IS TO UNBURDEN THE CUSTOMER, ENSURING THEY CAN CONFIDENTLY DELIVER PRODUCTS TO HOSPITALS, knowing we're overseeing production quality. Occasionally, issues arise with products in use, often for various reasons. Customers notify us if they receive such a report, and within 24 hours, we assess if patient safety is at risk. I'm pleased to say there's only been one case I know of and it didn't compromise patient safety. However, that analysis revealed that a component from one supplier lost functionality over time, so we adjusted it in the following production run and solved the issue.

In addition to product supply, we support customers in the commercial phase with post-market surveillance and annual supplier audits, both vital for ongoing product sales.

Our clients range from multinationals to startups. Working with large customers is, of course, rewarding. They have big orders, strong market placement, and streamlined service delivery. But partnering with startups is exciting, too; it's rewarding to guide them through growth challenges as they mature. One of our biggest clients recently awarded us an A rating for our service, which was a real boost. They appreciate being able to outsource the entire supply chain to us without concerns, saving them time and resources.

Currently, we have separate supply chains for each customer, a setup that typically stems from the R&D process. While it's understandable from a development standpoint, it sometimes feels like an arranged marriage from an Operations perspective. We're now working on involving Operations earlier in the development process so we can advise on supplier choices. This matters because development projects are relatively short, but Operations manages them long-term. In that sense, we're aiming for it to be 'true love.'

Ghinwa Karkes, Logistician:

Looking for irregularities

WE RECEIVE BOTH SEMI-FINISHED AND FINISHED PRODUCTS, AND IT'S OUR JOB TO INSPECT THEM. This involves checking the accompanying documents as well as the physical products. We verify product names, quantities, and dimensions, sometimes measuring them ourselves. For instance, we might open a package in the clean room and examine it with a magnifying glass for any irregularities. One time, I noticed several cages had small, brown spots. I photographed them and discussed the issue with our supplier, which led to further investigation by a quality engineer. It turned out the cages hadn't been properly dried before packing.

I joined BAAT in 2022 after working as a math teacher, and I really enjoy it here. The variety keeps it interesting; some inspections are done on the computer, and others are done hands-on in the clean room, dressed in protective gear. Occasionally, I examine products under a microscope to check for impurities, especially on sterilized items. Once, I found a stray hair within the sterile packaging. Of course, that product was rejected immediately."

Renate Herink, Supply Chain Coordinator:

Document completion, inspection and packing

MY COLLEAGUE TOM AND I OVERSEE ALL INCOMING ORDERS TO ENSURE THINGS ARE DELIVERED ON TIME. When implants arrive at BAAT, we inspect them and send them for packaging and sterilization, while instruments go directly to packaging. Once approved and packed, Quality checks the paperwork, and then they're ready for delivery to customers or for storage in our warehouse.

I also do periodic walkthroughs of our product facility to see what's there and check product conditions. Instruments often come in transparent bags, and it's fascinating to see these complex designs and I often wonder how on earth they are made.

I've been in Operations for almost two years, and there's a lot of interaction with other departments. You can't do this job alone. That connection makes the work enjoyable. Recently, the 'Ops' team visited our supplier in Germany for 3D-printed titanium implants.

Perfect porosity by 3D printing

Odmar Christiaanse

Optimal fusion of vertebrae

WHEN INSPINE AND BAAT MEDICAL LAUNCHED THE CELLULAR TITANIUM CAGES PROJECT in 2012, the interbody fusion surgeries, where a 'cage' is placed between spinal vertebrae to address damaged discs, had been performed for over 30 years. "An interbody fusion cage reconnects two vertebrae, eventually allowing them to grow together to form a large vertebra, restoring the stability of the back", explained Odmar Christiaanse, who joined the project on behalf of BAAT in 2015. Michiel Schwartz, Business Director of InSpine, noted: "As a distributor of medical implants, we offered a cage from a German manufacturer before 2012. But that product was sold off, leaving a gap in our portfolio." Looking for a replacement, which was simultaneously an upgrade, Schwartz ended up with 3D-printed titanium. InSpine partnered with BAAT, a company they had worked with previously and was also interested in 3D technology. "At that time, 3D printing for medical devices was still new", Schwartz explained. "But we knew it allowed for unique product properties." Among these was the ability to engineer the cage's elasticity to flex slightly and support movement rather than being rigid.

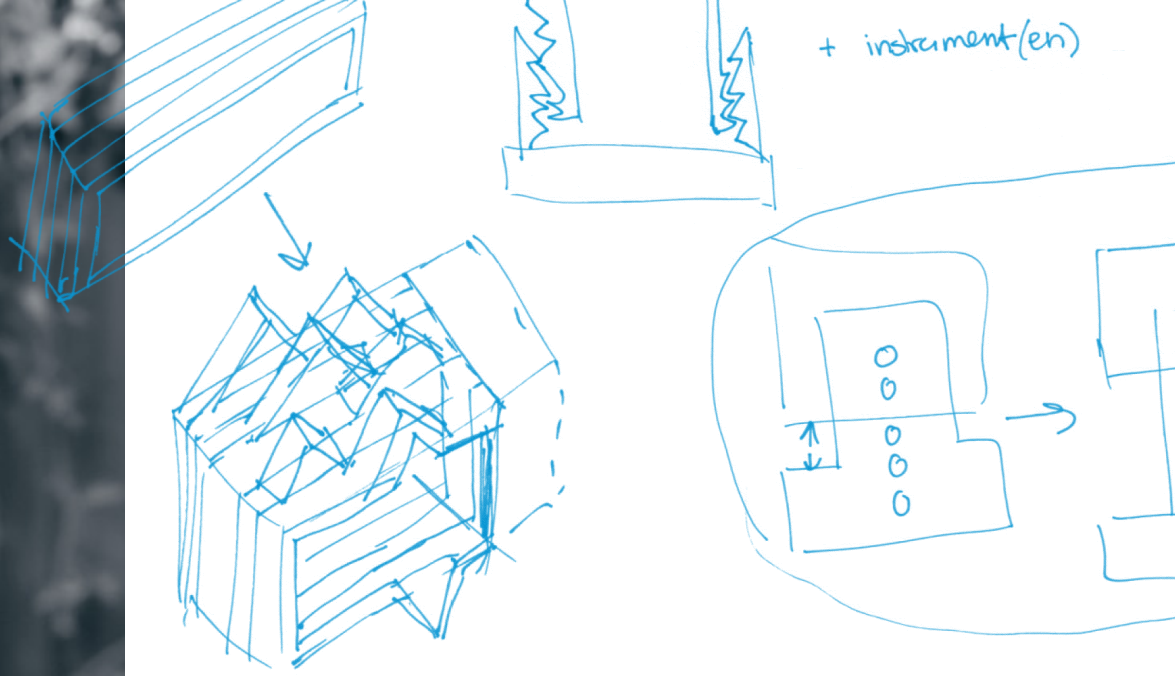
Product: ***CONDUIT Interbody Platform***
Customer: ***InSpine/EIT/Depuy Synthes, Schiedam (NL), Tuttlingen (DE), Warsaw (USA)***
Part of the body: ***Spine***
Start: ***2012***
Development: ***3 years, 4 months***

Product: ***LLIF Expandable Interbody Fusion Cage***
Customer: ***EIT, Tuttlingen (DE)***
Part of the body: ***Spine***
Start: ***2017***
Development: ***1 year, 6 months***

"THE CAGE'S POROSITY, ACHIEVABLE THROUGH 3D PRINTING, WAS EVEN MORE ESSENTIAL", Schwartz continued. "Tests showed our cage supported bone ingrowth significantly better than conventional products, providing improved stability." Additionally, BAAT had developed an innovative methodology for rapid CE marking of 3D-printed products, allowing for quicker market entry. So far, so good. Or rather, too good. The project's success quickly exceeded expectations. "Frankly, we were in over our heads", Schwartz admitted. "Nancy Lamerigts and the late Hans Eekhof, driving partners behind InSpine, founded EIT (Emerging Implant Technologies) with Guntmar Eisen to roll out their ideas on 3D printed spinal cages. Guntmar Eisen, the CEO, was someone BAAT had collaborated with before. EIT soon became a thriving German startup with a solid customer base."
BAAT also benefited from the project. Odmar reflected: "We designed and built the production process together with Layerwise, now 3D Systems. This experience brought both parties invaluable expertise in 3D printing for medical products. Something we had been pursuing for years already. It paved the way for many new orders and future opportunities."

A UNIQUE MILESTONE FOR BAAT AND EIT WAS GAINING ACCESS TO THE U.S. MARKET FOR THE CONDUIT product line. "Given the nature of the product, a long-term clinical trial would have been impractical", Odmar explained. "In the U.S., it's possible to launch a product similar to an existing one with the same treatment claims. This way, clinical relevance and patient safety are already proven, and a clinical trial is not required." We identified a comparable product, and, in a clever adaptation, non-functional holes were added to the cages to mirror its design. "It feels counterintuitive", admitted Schwartz, "you want to launch a product, and an alteration like that would lower the quality. But since these modifications didn't affect functionality, this approach enabled a quicker market launch."

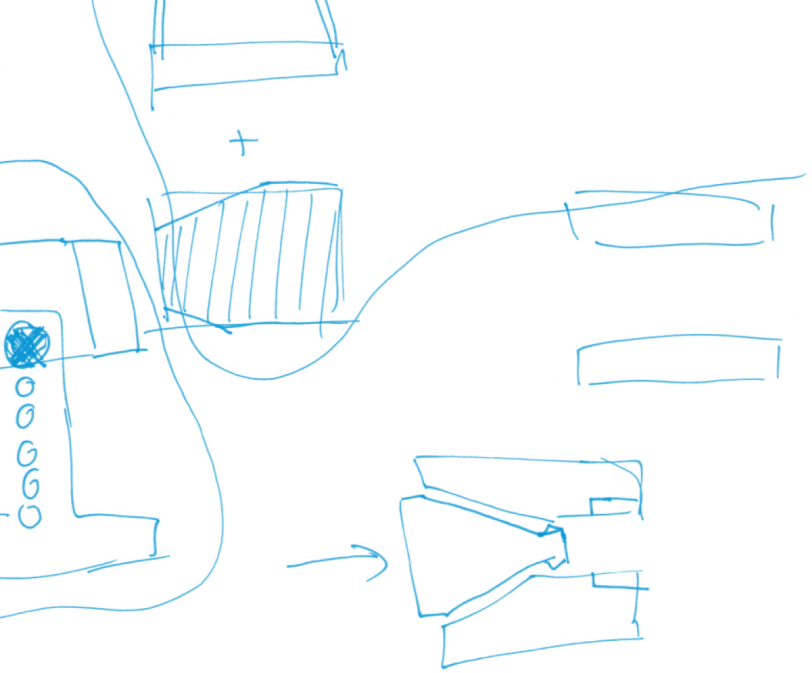
As the product gained traction, it caught the attention of major orthopedic companies, and one of them, DePuy Synthes, eventually acquired EIT. "Large companies are prepared to buy out competitors only to discontinue them", Schwartz explained. They make the superior product disappear. That way, their product isn't jeopardized. "But, to their credit, this



multinational didn’t ‘kill’ our product, in fact, they continue to carry and sell it in considerable volumes.”

WHILE EIT’S MAIN FOCUS WAS ON THE CONDUIT, Eisen was already working on a new project in 2017: an expandable cage for lumbar spine applications with limited access from the front or back. “With the working title LLIF XPAND, the cage needed to be inserted laterally, requiring a minimally invasive approach to prevent damage to muscle and nerve tissues and blood loss. Get in as small as possible and then fill as large an area as possible: it’s a contradictory task. Inserting it in a collapsed state and then expanding to fill the area fully was quite the engineering challenge”, explains Ryelle Endert, BAAT’s lead engineer on the project.

The LLIF (Lateral Lumbar Interbody Fusion) expandable cage brought more challenges. “Eisen had acquired a patent for the cage from an American doctor”, Endert notes. “Usually, as a designer, you work from a problem to a solution and then possibly apply for a patent. But we already had the

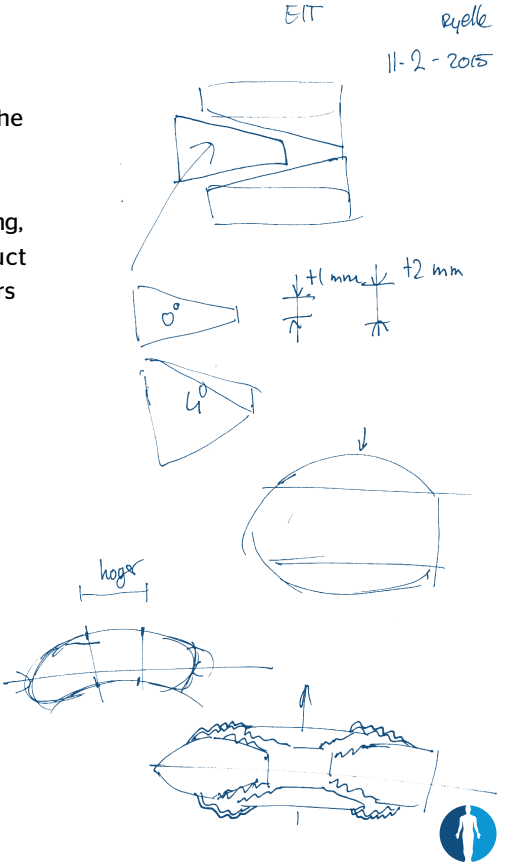


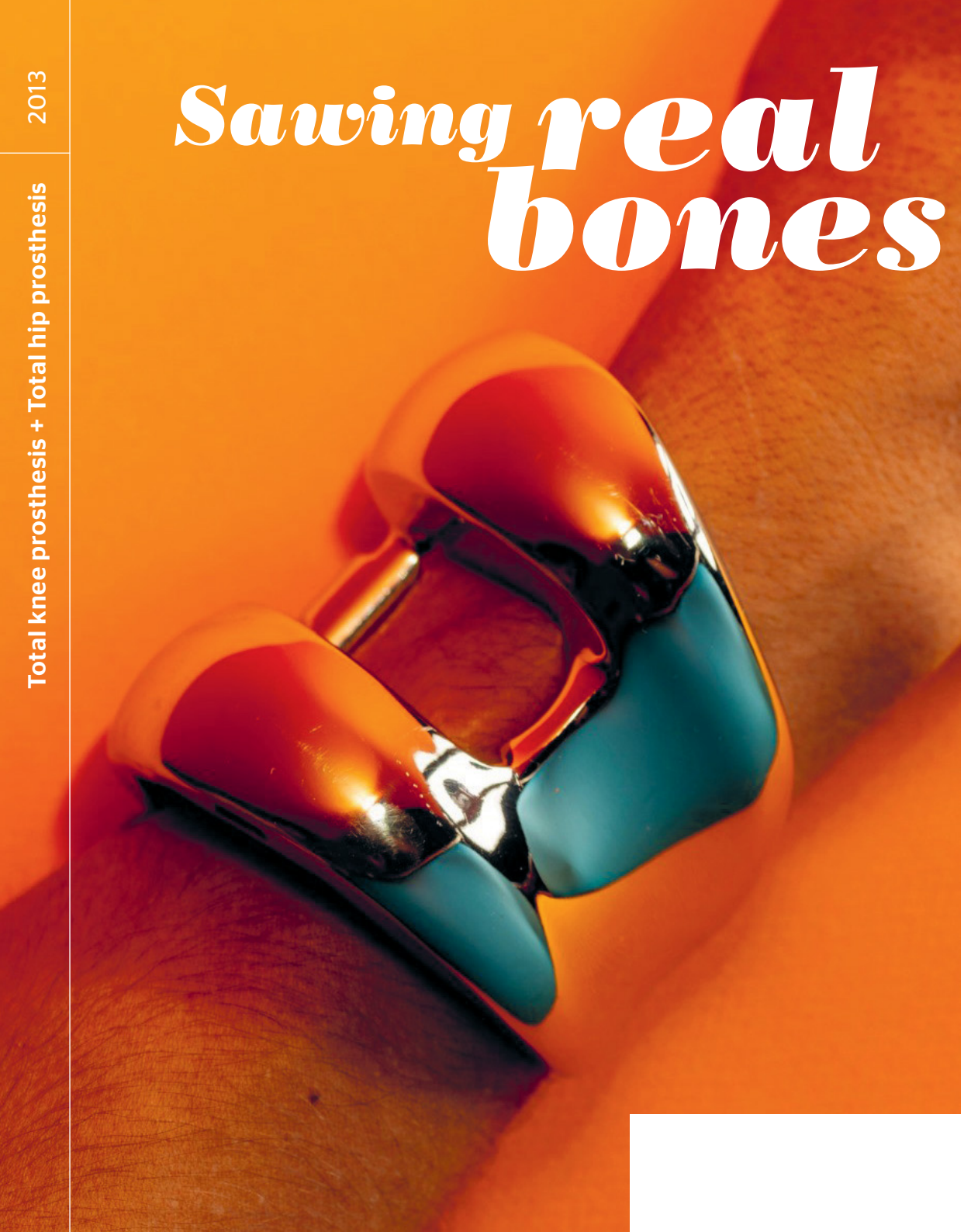
“The project’s success quickly exceeded expectations. Frankly, we were in over our heads”

Michiel Schwartz

patent and a sketch, which provided only a working mechanism, not a final product.” Eisens’ team had already determined that the cage was to be 3D-printed, meaning the hinged parts couldn’t be loose parts. Using relatively rigid titanium only added to the complexity. For U.S. market entry, the cage also needed to allow bone grafting like the existing ones. “Since this version was to be inserted in a collapsed form, filling could only occur post-insertion. Getting hold of human bone graft is difficult, so we had to be creative”, Endert laughs, “with garage soap and butcher’s bones, ground up like grated cheese to simulate bone graft.”

NUMEROUS CLEVER MECHANICAL SOLUTIONS LED TO A FUNCTIONAL FINAL PRODUCT. For example, the insertion device utilized a triple-tube design to insert, unfold, and fill the LLIF cage. The cage itself resembles a mouth. In its compact form, the ‘lips’ press together. Pressing on either side creates an O-shape, with two central parts that move toward each other and lock together. Endert: “The biggest risk with a cage like this is that it doesn’t lock properly, or that the surgeon doesn’t know if it’s locked. But once our insertion device is in a certain position, you can be sure the cage is expanded and locked”, explains Ryelle Endert. Reflecting on the experience, Endert concludes, “It was a massive learning curve for our team, involving brainstorming, testing, and daring to make mistakes. Although the product never reached the market, the project opened many doors for BAAT.”





Sawing real bones for finetuning

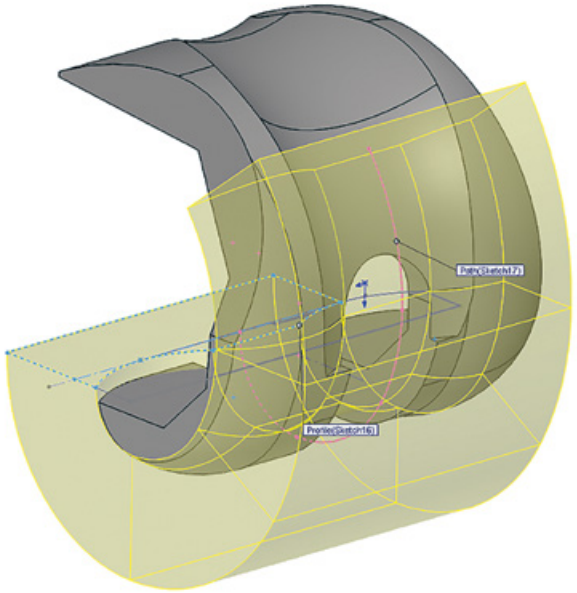
Replacing the knee or hip with a full prosthesis

IN 2013, SPANISH MBA SURGICAL EMPOWERMENT CONCEIVED A PLAN to develop its own knee prosthesis and hip prosthesis. Total knee and hip replacements are one of the most performed surgeries in joints in our aging society. MBA planned to have the product situated at their Berlin-based company, Human Kinetic. “We were looking for a partner to develop these implants and instrument sets and we had a very good feeling about BAAT”, says Francisco ‘Pachu’ Doblas, Chief Operating Officer at MBA at the time. “Honest, serious professionals operating at a very high level technically. We never regretted the decision to work together.”

According to Doblas, the entire BAAT team did a great job, led by Project Leader Martijn Heikens and with Arthur Aalsma as an all-round sparring partner. “The knee and hip replacements are typically for patients struggling with severe wear and tear or inflammation in the joint. Replacing their knee or hip with a prosthesis consisting of metal and plastic is the best solution”, explains BAAT Lead Engineer at the time, Jeroen Kunst. He had just graduated from his

Product: ***Total knee prosthesis***
Customer: ***Human Kinetic, Berlijn (DE) / MBA Surgical Empowerment, Gijón (ES)***
Part of the body: ***Knee***
Start: ***2013***
Development: ***2 years, 5 months***

Product: ***Total hip prosthesis***
Customer: ***Human Kinetic, Berlijn (DE) / MBA Surgical Empowerment, Gijón (ES)***
Part of the body: ***Hip***
Start: ***2014***
Development: ***2 years, 1 month***



biomedical studies, and BAAT allowed him to jump straight into the deep end: "I landed on this huge project, in which I was allowed to create the instrument sets. Thanks to BAAT's professional structure, it felt safe and was definitely a way to develop quickly."

THE KNEE PROSTHESIS WAS BASED ON A PRODUCT THAT MBA HAD ALREADY DISTRIBUTED. BAAT began reverse engineering the product and then made improvements to it. As for the instrument set, it was an upgrade from what MBA had already sold. Kunst: "A set like that consists of 264 parts and eight large sterilizable trays, so that's a huge task. All parts must be compatible with each other and with different types of knee implants (CR, PS, CU). It all has to work together. Including, for example, one handle that fits all instruments."

"It starts with developing the instruments on the computer. But then we need to know if everything feels comfortable and if a certain button is easy to operate. And whether, for example, body moisture also affects how it functions. So we make prototypes; in this case, we used 3D printing. It's a way to experience it ourselves and already resolve some of the teething problems—because there's always something. For example, we collected animal bones from the butcher to test our bone saws," Kunst explains. "It doesn't make us surgeons, but if we prepare properly, we can interact with the surgeons at a higher level on how to fine-tune the instrument set."

SOMETIMES THE INSTRUMENT SET IS THE NEGLECTED CHILD OF A PROJECT: virtually all of the client's attention often goes to the implant because, after all, that's where the money is made. BAAT pays attention to make sure the instrument set isn't an afterthought. Kunst: "The instrument set is always in the project and is always budgeted. And when a surgeon is pleased because they find they can work well with it, enthusiasm for the implant automatically grows." It is similar to a carpenter: they use each nail once, but their tools have to perform every day, again and again.


Francisco Doblas

“It doesn’t make us surgeons, but if we prepare properly,
we can interact with the surgeons at a higher level”


Jeroen Kunst

MBA gave Human Kinetic and BAAT two and a half years to set up this whole new system with knee and hip prosthetics, including instruments, packaging, sterilization, and getting everything in line with laws and regulations. “That was quite ambitious”, Doblas reflects. “But we achieved these goals.” Despite this, neither prosthetics made it to market, which was a huge disappointment. “It affected me personally”, Doblas acknowledges. “The prosthetics were ready for production, but MBA pulled the plug. Ultimately, the new management felt that the strategy of developing implants themselves — MBA was primarily a distributor — was too risky and too expensive.” This type of policy decision isn’t uncommon, but for Doblas, it was why he left MBA. For BAAT, it was also a pity that a large and well-run project like this ended early. Kunst says: “A knee replacement does not have eternal life, and as an extension of total knee replacement, we were already working on revising it. In fact, we had already come up with innovative solutions for that.”

Vincent Cloostermans

soft tissues in the knee joint

Deferral of a knee replacement

For some, wear and tear or osteoarthritis may make a knee replacement necessary, even at a young age. Yet, a new knee only lasts about 15 to 20 years for active, younger patients. “You don’t want to be on the operating table again at 50”, explains Vincent Cloostermans, R&D manager at BAAT Medical. “So, through physiotherapy and pain management, patients try to delay knee replacement surgery for as long as possible until it’s really not feasible any longer.”

AT UMC UTRECHT, A NEW CONCEPT CALLED KNEE DISTRACTION AROSE—a procedure that involves temporarily separating the knee joint surfaces, to allow damaged cartilage to heal, thereby delaying the moment when replacement surgery becomes essential. “We started using an off-the-shelf external fixator”, says Karianne Lindenhovius, working for UMC Utrecht in those days and now CEO of ArthroSave. “That one had a bulky, heavy frame not designed and meant for knee distraction. Nevertheless, the data was so promising that we decided to ask BAAT Medical to create a userfriendly, lighter, knee-specific version. That resulted in the KneeReviver.”

Product: ***KneeReviver***
Customer: ***ArthroSave, Culemborg (NL)***
Part of the body: ***Knee***
Start: ***2014***
Development: ***2 years, 6 months***

The KneeReviver is attached to the leg around the knee joint with help of bone pins drilled into the bone. It pulls the knee joint apart and functions as an unloader during a six-week treatment period, allowing the cartilage in the knee joint to recover and eliminating the pain of bone-on-bone contact. Many requirements were addressed while fine-tuning the device.
"First of all, the KneeReviver had to have much less weight, you had to be able to operate safely and faster with it, and it had to remain affordable", Lindenhovius explains.

Cloostermans adds: "We wanted patients to live as normally as possible while using it—able to walk, shower, and not feel anxious just looking at it. And it needed to be reusable. All of these elements were key considerations in development." Lindenhovius highlights another point: "For optimal force distribution, it was important to drill pairs of two pins into the bone simultaneously and parallel. It required significant effort within the project to get that done. This kind of technical hack has even earned us some patents."

With insights from surgeons and patients, the KneeReviver evolved into a fully functional product within two and a half years. It has since been used successfully in the Netherlands at ten hospitals, with more than two hundred fifty patients today delaying knee replacement surgery as a result. "We hope that the procedure with the KneeReviver can be repeated after a few years", says Lindenhovius.

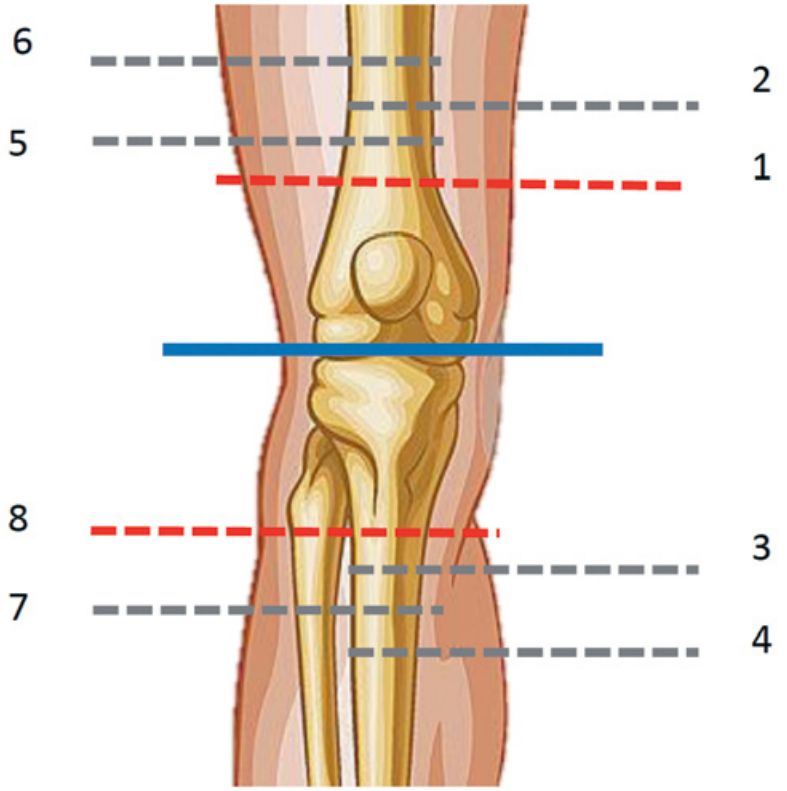
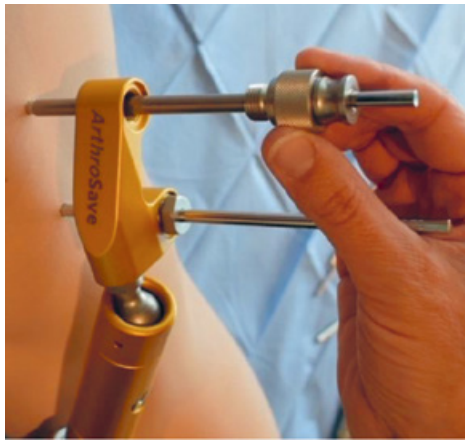
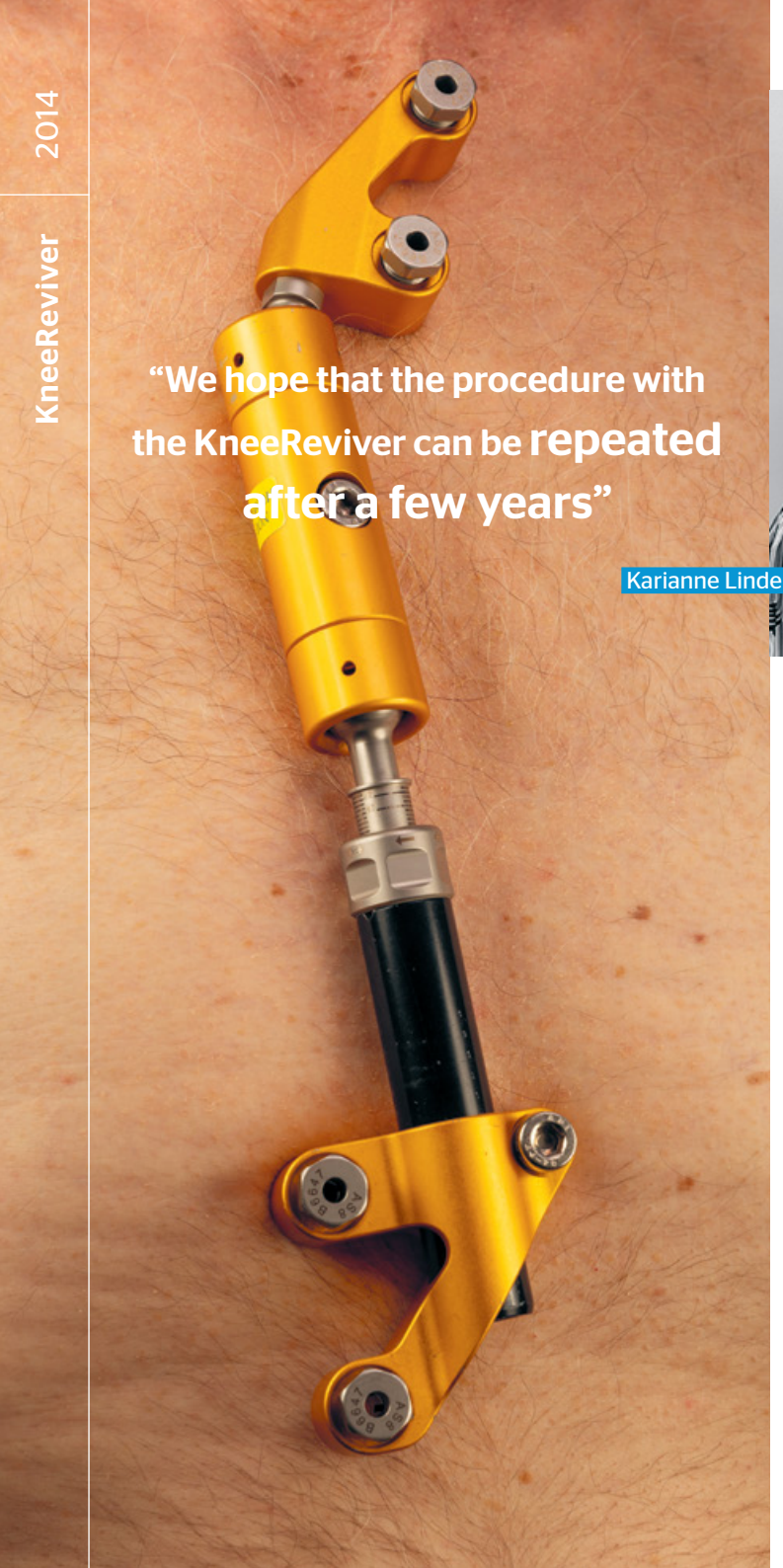


Figure 14 Knee markings; parallel to the joint space outside the synovial cavity





“We hope that the procedure with the KneeReviver can be repeated after a few years”

Karianne Lindenhovius

“That would be interesting to investigate in the future.”

ARTHROSAVE IS A SPIN-OFF COMPANY OF UMC UTRECHT that was founded in 2016 specifically for the commercialisation of the KneeReviver, with Lindenhovius as CEO. BAAT and ArthroSave agree that their collaboration has been worthwhile. “Fortunately, the academic inclination to keep researching indefinitely didn’t slow us down here”, Cloostermans laughs. The process wasn’t without obstacles. The insurance companies threw a spanner in the works despite the exclusively positive patient results. They were reluctant to reimburse the KneeReviver treatment, not due to doubts about its effectiveness but because of the high standards for new treatments. “They felt our patient clinical data wasn’t sufficient and wanted more clinical evidence”, Lindenhovius notes.

Fortunately, everything’s coming together after all. “And that is very special”, Lindenhovius beams. In fact, the government has made ten million in funding available for a randomized clinical trial with 1,200 knee patients to assess the treatment for reimbursement. This trial is known as the GODiVA trial. “Half of these patients will receive a knee replacement and the other half will undergo a knee distraction. We expect this trial to validate our findings of reduced osteoarthritis, improved knee function, and sustained pain relief.” Ultimately, the icing on the cake would be treatment reimbursement, putting the KneeReviver within reach for many patients.

What is typically BAAT?

Angelique van Leeuwen:

"My favorite day isn't Saturday or Sunday, it's Monday, because it means I have another full week of new activities and challenges ahead of me."

"I love the mix of projects. If I get stuck on one, I can just pivot and dive into another. Then when I come back to the tricky project, I've got forty colleagues right there, all accessible and ready to help."

A brand new

Product: ***Verticale Triangular Fixation***
Customer: ***Silony Medical, Leinfelden-Echterdingen (DE)***
Part of the body: ***Pelvis/back***
Start: ***2016***
Development: ***2 years***

pelvis fracture system

Precision screw placement to stabilize the pelvis

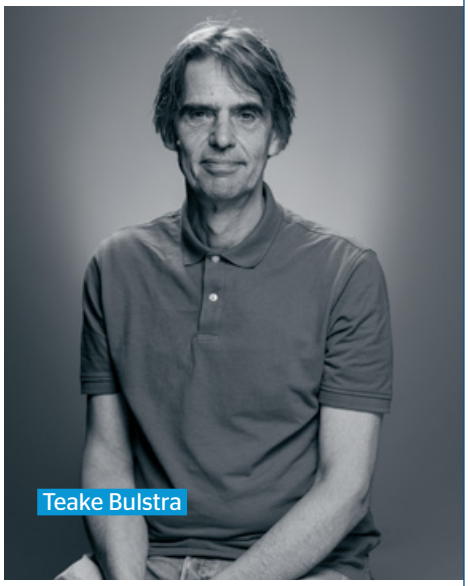
PROJECT MANAGER TEAKE BULSTRA BREAKS INTO A SWEAT. *Silony, the German medical products distributor, has organized a preliminary meeting in an impressive hotel in Frankfurt. The presentation of their idea for a new screw to fix the pelvis to the sacrum is a big deal. "The three doctors, two traumatologists and an orthopedist, sitting there representing Silony, already had a specific idea for the screw: a certain length, a certain width, and an innovative plate to better fix it, and they also indicated the placement. So, could we please make that?"*

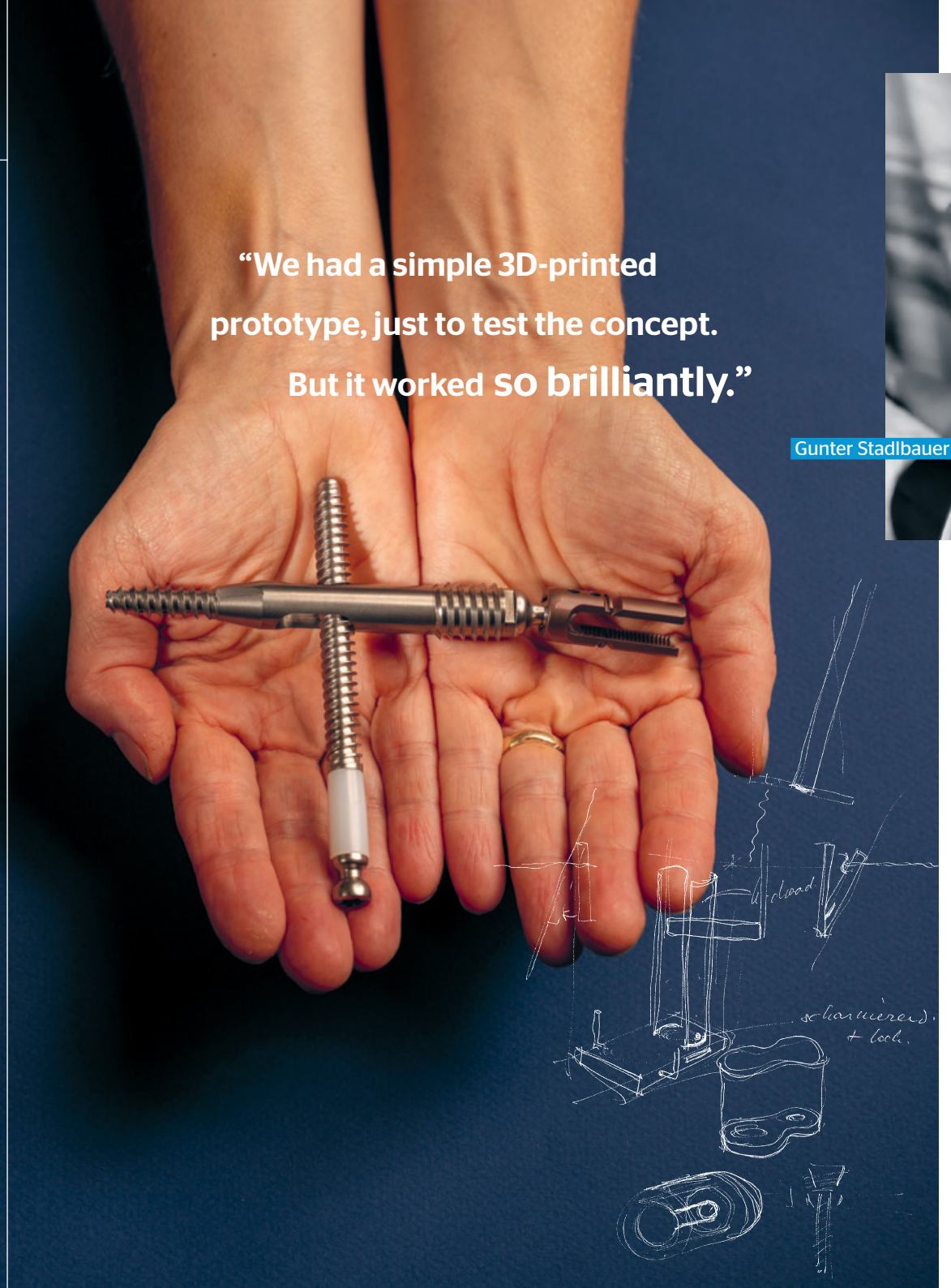
"It's often like that", Bulstra explains. "A customer approaches us with a good idea and already has the solution ready in their mind. It's our job then to find out if that solution is the best solution for their problem. This was what we did in Frankfurt. The first two meetings involved asking a lot of questions. "We're not orthopedists and unfamiliar with the OR, so we must understand the surgical procedure. And they aren't engineers. If you design exactly what the customer thinks they want, you will run the risk that it won't work, and they won't be satisfied.

The sweet spot is right in the middle. When you're no longer thinking in terms of client and contractor, but joining forces to create a good product together for the patient."

IN THIS CASE, WE WERE DEALING WITH PATIENTS WITH PELVIC FRACTURES OR SEVERE PELVIC INSTABILITY due to old age, pregnancy, or an accident. "The traditional procedure is to fix the pelvis to the sacrum using a long screw. The surgeon determines approximately where the screw should go based on X-rays. If it's not quite right, he puts in another and then another just to be sure", Bulstra explains. Since there is a very narrow corridor through which the surgeon can place the screws, it's a risky procedure. There is a risk of paralysis if the nerve pathways are touched or, for example, a risk of additional fractures for older people with brittle bones.

One of the traumatologists came up with the idea to make the corridor determination more accurate and fix the screw to the outside of the pelvis with a plate. Distributor Silony saw the potential in this if they could combine it with their


Teake Bulstra




Gunter Stadlbauer

own screw for fixation of the pelvis to the spine. They asked BAAT to design the horizontal screw. Project Manager Gunter Stadlbauer: “Because the BAAT team kept asking critical questions, it became clear that it was not going to be that straightforward.”Due to the considerable pressure on the sacrum, which bears eighty percent of our body’s weight and must also be able to hinge, the screw ‘wandered’ out. And the combination with the vertical screw made the correct positioning of the horizontal screw even more critical. “What started as a small project became huge.”

It earned him lively discussions with his CEO, who only understood the substantial budget excess when he saw the final results. “As a team, we were so focused on the best solution in terms of concept and design that we both lost sight of the cost”, Stadlbauer explains. “That could have gone better. But the CEO was very pleased with the result.”

Finishing Touch

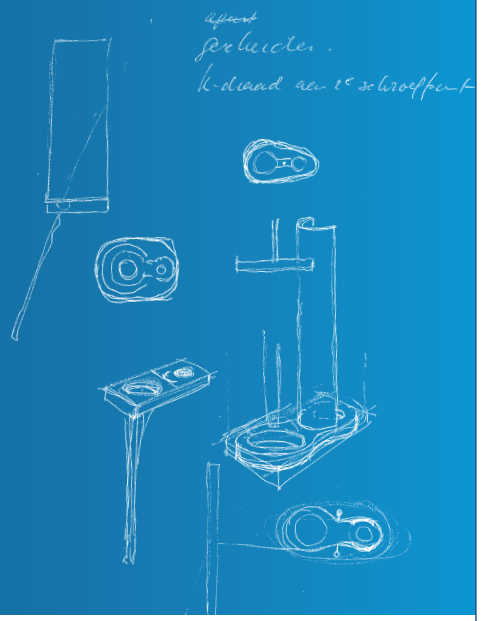
Verticale Triangular Fixation includes a set of screws of different lengths with a fold-out anchor attachment and a triangular construction of a screw within a screw. The finishing touch is a carbon measuring instrument that can be attached to the pelvic rim allowing the orthopedist to place the screw connecting the pelvis to the sacrum in precisely the right place.

IT REFLECTS THE CLIMATE IN WHICH THE SYSTEM WAS DEVELOPED. Stadlbauer: “The collaboration was fantastic. The people at BAAT are very fast in design and construction work.” To him, the second cadaver test session was a magical moment. “We had a simple 3D-printed prototype just to test the concept, but it worked so brilliantly.” Bulstra remembers that too: “That moment when a complex project falls into place. We were all working away in the same lab coats, big smiles on everyone’s faces because we had succeeded. It was complete.”

Perfect Preparation

“The pelvic fracture system was my first complex instrument design and also one of the first projects I witnessed from the start (idea on beer mat) to finish (approved for use). I can still picture Gunter coming to the cadaver sessions with a folder of literally all the drawings and everything neatly arranged with Post-its under his arm. Perfect preparation and accurate notes, which we could copy.”

Maarten Pijper
Lead engineer BAAT



Charm and frustration: the challenge of innovation

Fixate facet joints with a bioresorbable plastic

THE WOOD INDUSTRY COMMONLY USES A TECHNIQUE CALLED 'WOOD WELDING', which involves placing plastic between two pieces of wood and melting it to dissolve into the wood's pores, binding the pieces without screws. SpineWelding, based in Schlieren, Switzerland, saw potential beyond wood applications for companies like IKEA, for example, and envisioned applying this technology to the human body. After all, bones are porous, just like wood. Using a bioresorbable polymer that doesn't have any biological effects on the body and fully dissolves in time eliminates the need for removal by surgery.

The Turis Facet Fuser became the initial test case. "A facet joint is a small joint in the spine that allows the vertebrae to move in relation to each other", explains Tess van Dam, project manager & clinical research specialist at BAAT. "If a patient has facet joint-induced problems, it's usually fixed with metal screws and rods. SpineWelding saw bone welding as an innovative way to stabilize the joint. The Swiss company approached BAAT, and Van Dam remembers this project generated a lot of enthusiasm in Hengelo. It was a challenge, and that's always like throwing bait to pioneering engineers.

Product: ***Turis Facet Fuser***
Customer: ***SpineWelding, Schlieren (CH)***
Part of the body: ***Spine***
Start: ***2016***
Development: ***1 year, 10 months***

Dr. Barbara Frösch

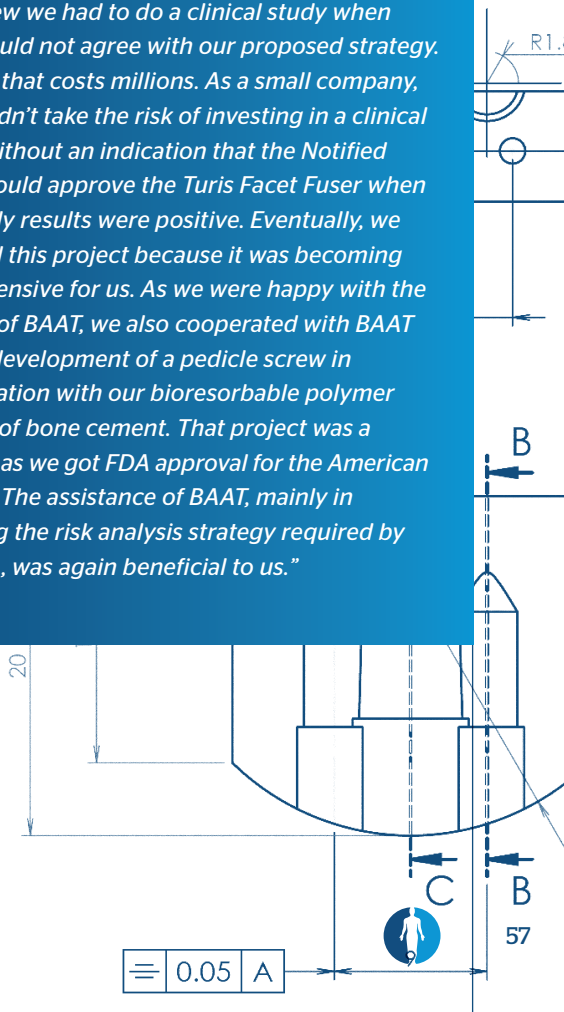
Manager Medical Affairs Spinewelding

"The cooperation with BAAT was great, but we were disappointed with the Notified Bodies in Europe. They had virtually no experience in the field of resorbable implants, were unable to ask the right questions nor willing to listen to our experts. Their clinical pathway review was a farce. Basically, they went for zero risk at that time, with the transition to the new, much stricter rules of the MDR coming up."

"We knew we had to do a clinical study when they would not agree with our proposed strategy. A study that costs millions. As a small company, we couldn't take the risk of investing in a clinical study without an indication that the Notified Body would approve the Turis Facet Fuser when the study results were positive. Eventually, we stopped this project because it was becoming too expensive for us. As we were happy with the service of BAAT, we also cooperated with BAAT on the development of a pedicle screw in combination with our bioresorbable polymer instead of bone cement. That project was a success as we got FDA approval for the American market. The assistance of BAAT, mainly in covering the risk analysis strategy required by the FDA, was again beneficial to us."

"IN 2016, WE ALREADY HAD EXTENSIVE EXPERIENCE WITH SPINAL IMPLANTS, but this was different from our other spinal implant projects", Van Dam continued. "The implant is made from a bioresorbable polymer, allows fusing of vertebrae, and then dissolves in the body. The advantages over screws, pins, and rods, which can cause irritation or inflammation, seem obvious." However, there was an immediate restriction to the project: SpineWelding wanted to proceed without requiring an — inevitably costly — clinical trial. "In terms of Medical Device Regulations, that was virtually impossible given the level of innovation. We were aware of the risk that the Notified Body would not accept a non-clinical validation strategy. But working with a bio-resorbable material, there was a lot for us to learn from that."

BAAT responded by setting up a rigorous testing plan to meet the safety and performance standards without a clinical trial. "It was a challenging strategy and I was not sure if it was going to be accepted", Van Dam recalls. "We conducted extensive research on bioresorbable implants, biological safety, and mechanical performance, using every resource and bit of creativity we had to meet compliance." The final litmus test took place in Arnhem, where Van Dam presented BAAT's findings to the Notified Body the day before her summer vacation. Despite her best efforts, the Notified Body did not approve the strategy without a clinical trial. "As expected, they couldn't justify approving it without additional data. Fortunately, the client understood that too. Despite the negative result, the Swiss company valued the work performed. "They, too, had this outcome in the back of their minds all along. And the route we took gave SpineWelding useful insights for their future."



2016

Turis Facet Fuser

“This was different from our other spinal implant projects. The implant is made from a bioresorbable polymer, allows fusing of vertebrae and then dissolves in the body”

Tess van Dam

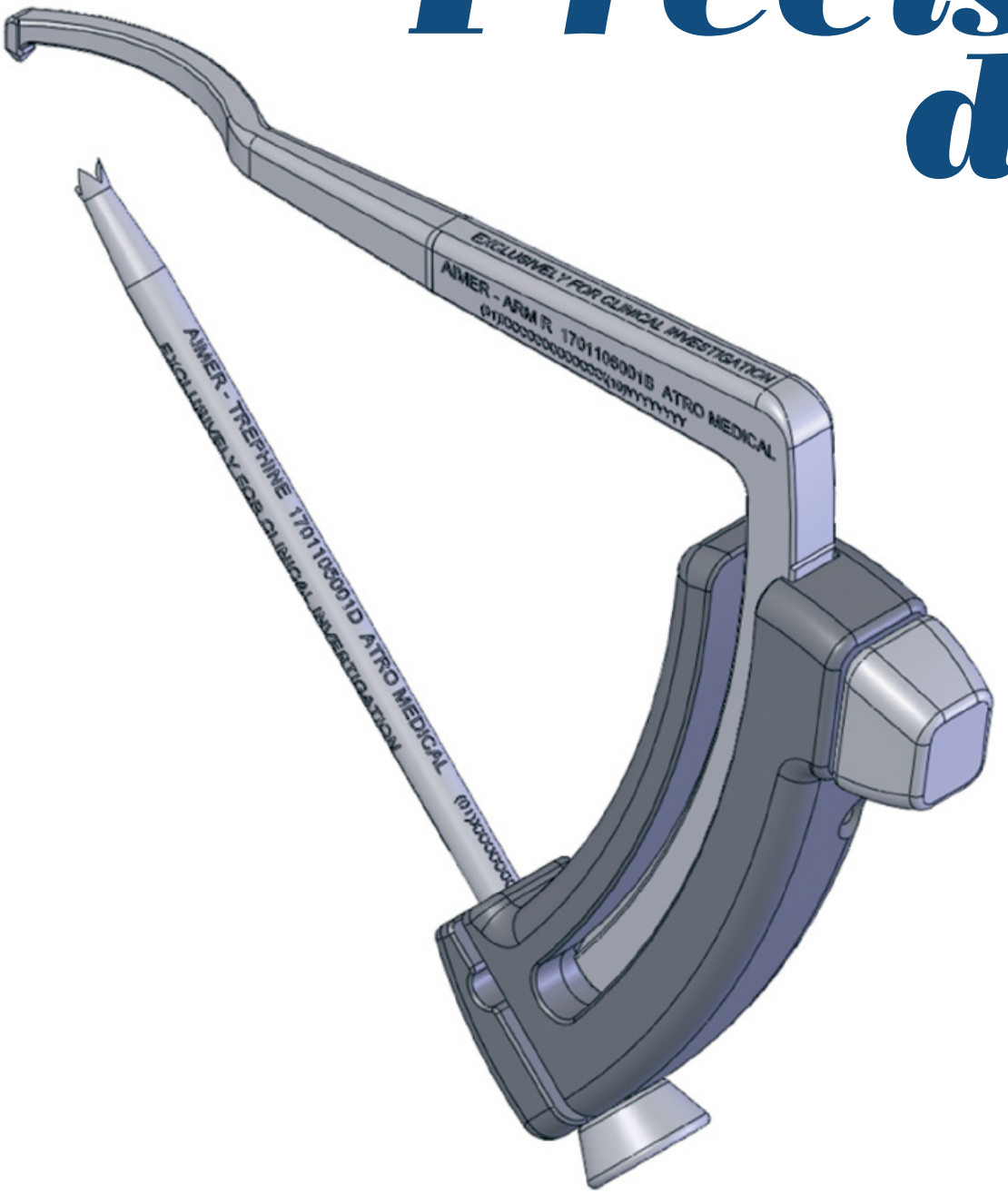
What is typically BAAT?

Cindy Rikhof:

"I just joined BAAT this summer, and I've noticed it has a great mix of people and ages. There are definitely more men than women but this doesn't impact our culture. I view BAAT as an inclusive working environment where gender does not dictate influence or opportunities."

"In my previous job, I conducted research at a rehabilitation center, where the focus was primarily on the research itself. It's different now, the emphasis is more on me and my personal development. To get up to speed, I'm taking lots of courses, call it my starter pack. Additionally, through monthly meetings, there's time to look at what I would like to do, how I can use my strengths, and what I want for my own growth."

Precision drilling



Pain relief in the knee joint

RUNNING AND JUMPING PLACE SIGNIFICANT STRESS ON KNEE CARTILAGE. Fortunately, the meniscus, which acts as a 'shock absorber', helps cushion these impacts. However, this fragile disc can tear, leading to severe pain. While initial treatment may involve removing part or all of the meniscus, this approach can accelerate knee wear and increase the risk of osteoarthritis and chronic pain. In some cases, it may even require a knee replacement, a major and invasive surgery. Since 2017, orthopedic surgeon Tony van Tienen and his company, ATRO Medical, have been developing a better alternative: the Artimis. This artificial meniscus aims to prevent further wear on the knee, distribute joint load, and significantly reduce pain. Moreover, the Artimis can be implanted through a minimally invasive procedure and is designed to last a lifetime, thanks to its durable polycarbonate urethane material.

For this project, BAAT primarily focused on the instrumentation needed to secure the artificial meniscus to the knee while also contributing to the early design phase of the Artimis. "BAAT helped us translate my ideas into a tangible product,

Product: ***Artimis Artificial Meniscus Instrument***
Customer: ***ATRO Medical, Nijmegen (NL)***
Part of the body: ***Knee***
Start: ***2017***
Development: ***2 years, 4 months***

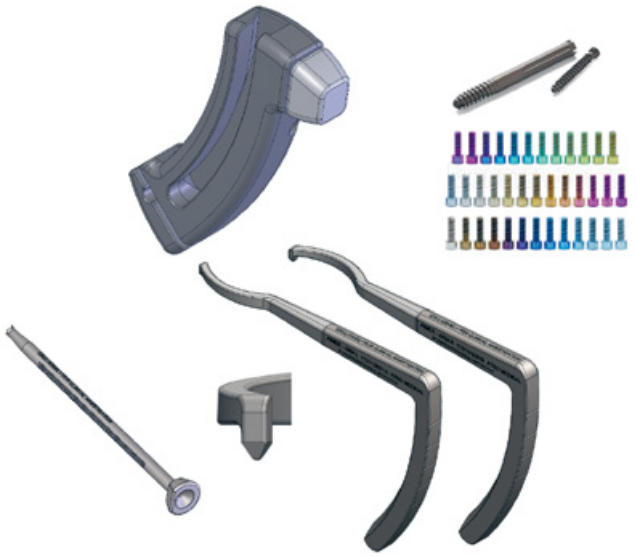
including the fixation and instrumentation", says Van Tienen. "They also converted our drawings into a specific file type required for manufacturing, and our implants were stored by BAAT during this period, which involves adhering to numerous guidelines they are well-versed in."

INITIALLY, THE ARTIMIS WAS SECURED WITH SCREWS, A DESIGN PERFECTED BY BAAT. However, ATRO Medical later opted for a different fixation method for a subsequent version of the artificial meniscus, while BAAT remained involved in developing the necessary surgical instruments. "In close consultation with the customer, we designed the alignment tool for drilling the holes", explains BAAT's Project Engineer, Erik Huizing. "The meniscus must be inserted at a specific spot in the knee, so the instrument needs to be extremely stable and precise. It features an eye at the end to help the surgeon know exactly where to drill. This is done manually, and the alignment tool ensures that the drill hits the right spot."During the Artimis development, BAAT also participated in cadaver tests, which Huizing attended. "A cadaver test is an invaluable learning experience

Direct Lines

"A medium-sized company with a flat structure, a collegial atmosphere, and direct lines of communication." This is how Erik Huizing characterizes the corporate culture at BAAT, where he has felt perfectly at home as a Project Engineer for over ten years. He joined BAAT through a secondment agency after completing his mechanical engineering studies. "I had no medical background, but over the years, I gained the necessary knowledge through the projects I worked on."

Erik Huizing



You might passionately develop a good product, but you're also dependent on market conditions and regulations"

Tony van Tienen

that sparks new ideas for product development", he states. "We take advantage of this opportunity to advance the project, and from an anatomical perspective, it's very educational to see how complex implant placement can be amid all the tissue, ligaments, and muscles."

ATRO Medical not only benefited from BAAT's technical expertise but also from its experience in bringing such implants to market. "For us, that was new and complicated, while BAAT had prior experience with that process", Van Tienen reflects. "They were immensely helpful in that regard." The collaboration began before their professional relationship, as Van Tienen has known BAAT's executive duo for many years. "Like Arthur, I often visited the Orthopedic Research Lab at Radboudumc, and over the years, I regularly brainstormed with him and Gert about developing and introducing orthopedic products. At that time, we didn't have concrete plans for implants and instruments; we mostly discussed possibilities. Later, I helped them with other products, such as providing input from an orthopedist point of view for developing a knee prosthesis."
"What's inherent in this work is that you must address all aspects, not just the technology. You might passionately develop a good product, but you're also dependent on market conditions and regulations." Fortunately, the prospects for the Artimis look promising. "We are now in the clinical trial phase, and so far, the results have been encouraging", Van Tienen shares. "The implant has undergone several design iterations, but we're on the right track with the current design."

Lifting the facet with a duck bill

Relieving pressure on the nerves by restoring the facet joint anatomy

NECK VERTEBRAE EXPERIENCE SIGNIFICANT WEAR AND TEAR. “It’s like a car”, explains BAAT employee Jordi Borst, who has been involved in developing the Facet Fusion Device in recent years. “If you’ve driven a lot, you’ll need to replace tires, shock absorbers, or repair other parts. The same goes for your vertebrae.” This wear can lead to crushed nerves, causing severe pain and loss of physical capacity; some patients may even struggle to use their arms properly. Additionally, this pain can disrupt sleep, severely impacting overall quality of life.

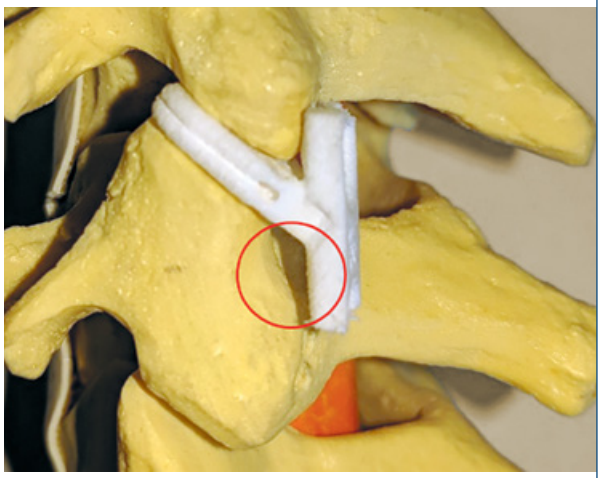
One effective solution involves placing cages—metal or plastic spacers between two vertebrae, replacing the intervertebral disc to restore anatomical alignment. However, a more innovative approach is to put a wedge between the facet joints at the back of the vertebrae. This method has the advantage of using smaller wedges to relieve pressure on the nerves, making the surgery less invasive. It requires less muscle removal, thereby minimizing damage to surrounding tissue.

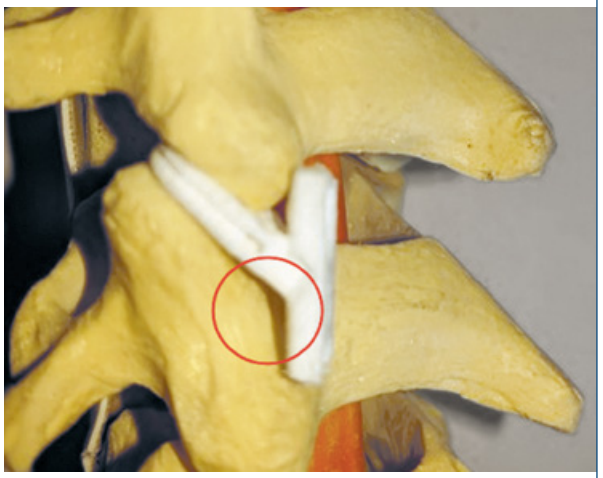
Product: ***Facet Fusion Device***
Part of the body: ***Neck***
Company: ***King Saud University, Riyadh (KSA)***
Project start: ***2018***
Development: ***4 years***

“OUR FACET FUSION DEVICE IS BASED ON THIS PRINCIPLE”, says Borst, who has worked on it primarily as an engineer and project manager. “It’s a titanium implant created using 3D printing technology. As the name suggests, the facet joint fuses, ultimately preventing movement between two vertebrae. The design resembles a duck bill; when closed, it can be easily inserted into the facet joints without causing damage. Upon opening, it creates a wedge effect that releases the nerve.”

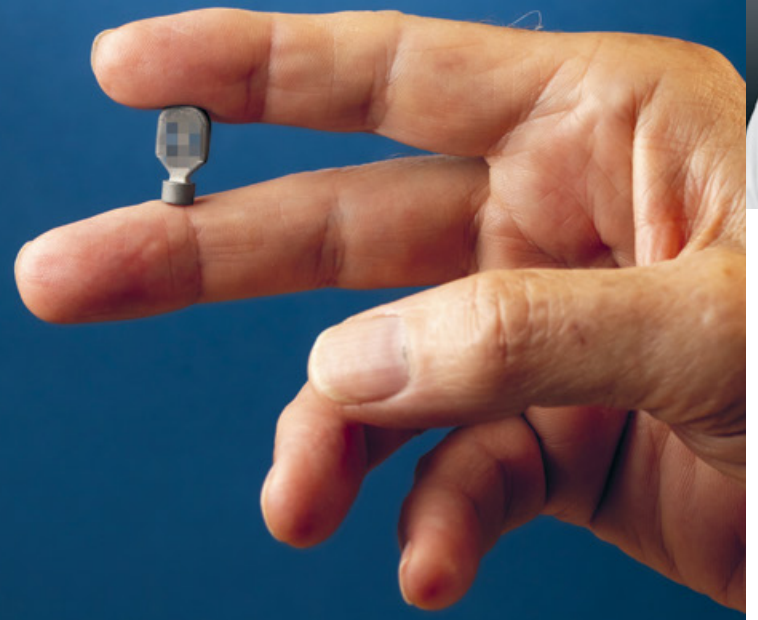
The concept for the Facet Fusion Device originated from the University Hospital of King Saud University in Riyadh, Saudi Arabia. “The customer approached us with a concept”, Borst recalls. “The thing is, at BAAT, we’re quite headstrong and felt we could enhance it. So, unlike the original design, we developed a new concept that can be printed in one go. It’s quicker to install because it’s thinner but offers more jacking power than the first version. The customer was very enthusiastic about it”, he concludes, appreciating the collaboration. “As project manager, I maintained bi-weekly contact with them about the project’s progress, which they appreciated. They are polite, knowledgeable individuals who are genuinely interested in our company and enjoy working with us.”

DR. AMRO AL-HABIB, HEAD OF THE UNIVERSITY’S NEUROSURGERY DEPARTMENT, AGREES: “BAAT understands what we want. They possess extensive technical knowledge and expertise in spinal surgery devices, particularly for the vertebral column. They can test prototypes in-house and send them to us, which is effective because they can incorporate our feedback and modifications. They also know what materials the device should be made of, how to package and sterilize it, and which European standards it must meet. Their comprehensive awareness of the entire process is invaluable to us.”





“Mr. Gert visited us in Riyadh, and it was both a productive and enjoyable experience”



Amro Al-Habib

Dr. Al-Habib also appreciates the personal relationship he has developed with BAAT. “They are professional and meticulous but also very friendly and warm”, he shares. “Mr. Gert visited us in Riyadh, and it was both a productive and enjoyable experience. We discussed project planning, and he toured our hospital, but there was also time for good food and some sightseeing. Building personal relationships like this makes collaboration easier later on.”

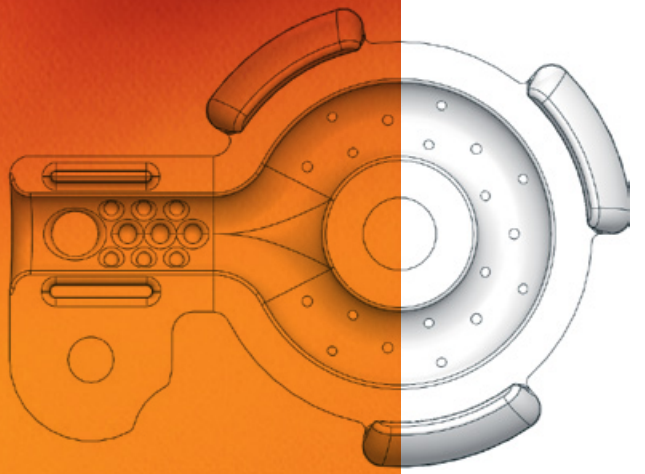
CURRENTLY, THE PROJECT IS IN THE CLINICAL TESTING PHASE. “We just received approval for a clinical trial in Saudi Arabia”, Borst states. “If all goes well, it will pave the way for larger studies, and the device could eventually be used in practice. However, that might take some time.”

What is typically BAAT?

Tess van Dam:

"When I joined BAAT, the legislation was about to change. With a background in biology, I approached this challenge to align our clinical validation with the legal requirements systematically, and step by step made it my expertise. Engineers can't be bothered with the legislation stuff, but I see it as a little island with many bridges connecting to other departments. We rely on each other: I need them, and they need me. This collaboration is what makes my work so enjoyable and dynamic, I get to be involved in every project, even if it's just for a short time."

Grow some nerves

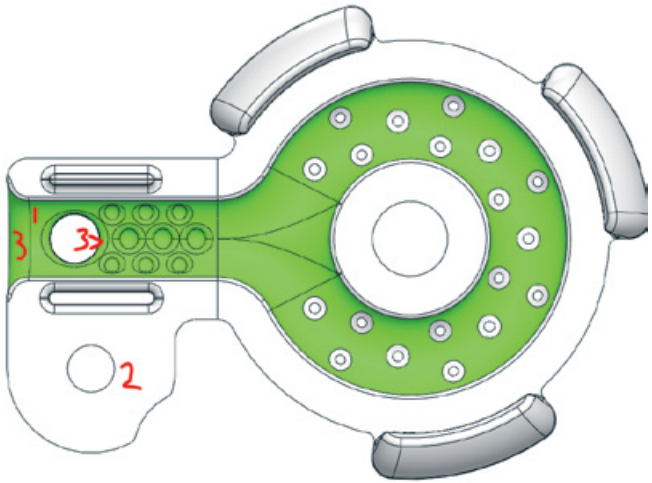


Relieving pain by preventing neuromas from growing on severed nerves

SEVERED NERVES CONTINUE TO GROW UP TO A MILLIMETER A DAY. If the severed nerve ends are close enough together, nerve fibers coming from one end can grow back into the other end to restore function. But if the gap is too large and the fibers cannot reach the other end, a disorganized bulb of growing nerve fibers may form, which is called a neuroma. This nodule may be extremely painful for the patient and in case of amputation, the pain may be so severe that the patient cannot wear a prosthesis. Neurosurgeon Godard de Ruiter is among those in the medical field who have, for years, been looking for an effective way to eliminate and prevent neuromas. “The current standard is to surgically remove the neuroma and then bury the freshly cut nerve end into a muscle”, he explains. “But it’s better to give the nerve something to grow toward and avoid that the neuroma forms again.”

De Ruiter came up with the idea of the Nerve Stop: “You create a closed loop at the nerve end using a small extra segment that you first remove from the injured nerve, called an autograft”, he explains.

Product: ***Nerve Stop***
Customer: ***Godard de Ruiter, The Hague (NL)***
Part of the body: ***Nerves***
Start: ***2019***
Development: ***Still ongoing***



To solve this he developed a Y-shaped cassette made of two parts, a top and a bottom part. First you place the nerve end and the autograft into the bottom part, then the top part over it and you close it. “Nerve fibers coming from the nerve end can grow through the Y-tube into the autograft from both sides and are trapped in the graft, which has been shown to prevent neuroma formation.” The material of the cassette is bioresorbable and after the nerve has grown into the autograft the cassette will degrade in the body over time. The same procedure is used after amputation of a leg, to connect the two main nerves in the leg: one to lift the foot and the other to bend it. These are also connected using an autograft, forming a loop in a U-shaped cassette.

IN 2018, DE RUITER PRESENTED HIS IDEA TO THE DUTCH COMPANY INSPINE. “They directed me to BAAT,” said De Ruiter, who practices at the Haaglanden Medical Center in The Hague. “We clicked immediately. Gert Nijenbanning was enthusiastic but also kept me grounded. Even the best ideas don’t always succeed, especially with the high cost of bringing a product to market. So, we agreed to split the project into phases and address it step-by-step. First, we needed to assess whether the Nerve Stop was patentable. Once we confirmed it was, we moved forward. It’s been a fascinating process that still has me collaborating with BAAT.”

One of the team members involved in this project is Project Manager Teake Bulstra, who shared Nijenbanning’s balanced optimism. “He came with creative solutions for potential practical problems of the cassette”, De Ruiter recalls. “For example, what kind of mechanism would you use to snap the cassette shut? How can we ensure the severed nerve segment gets enough oxygen and nutrients? And how do we keep it small enough to avoid discomfort for the patient? BAAT found answers to questions like these.”

THE PROJECT HAS REACHED THE INITIAL TESTING STAGE, thanks partly to BAAT’s Tom te Stroete, who works on the Nerve Stop as lead engineer. “Our team focused not only on the design but also on the choice of materials. The cassette had to be bioresorbable, which we had experience with from previous projects at BAAT. We ultimately chose a


Godard de Ruiter

A Personal Touch

According to Godard de Ruiter, BAAT’s customer and service approach is evident in the details. “Teake Bulstra lives ten kilometers from me and once cycled over to personally deliver prototype cassettes. That’s an hour round trip. We even had a beer together. Most of my interactions with the rest of BAAT are on Teams, but I like that too.

bioresorbable polymer. Then, we explored manufacturing options with a Swiss company, looking at 3D printing and injection molding. Injection molding provided the higher product quality we wanted. The downside was the high cost of molds, which increased production costs significantly. We solved this by creating a mirrored design so we could use a single mold for both halves of the cassette.”

Further testing and validation are still needed before the product can reach patients. Te Stroete comments: “As we continue developing, we’re keeping customer needs front and center without losing sight of the risks. Ultimately, we only want to release a product we fully stand behind.”

A set for minimally invasive

Product: ***KG2 Interbody Spinal Fusion System***
Customer: ***Kleiner Device Labs, Nevada (US)***
Part of the body: ***Spine***
Start: ***2019***
Development: ***1 year, 11 months***

spine surgery

Disposable set which enables effective bone graft filling

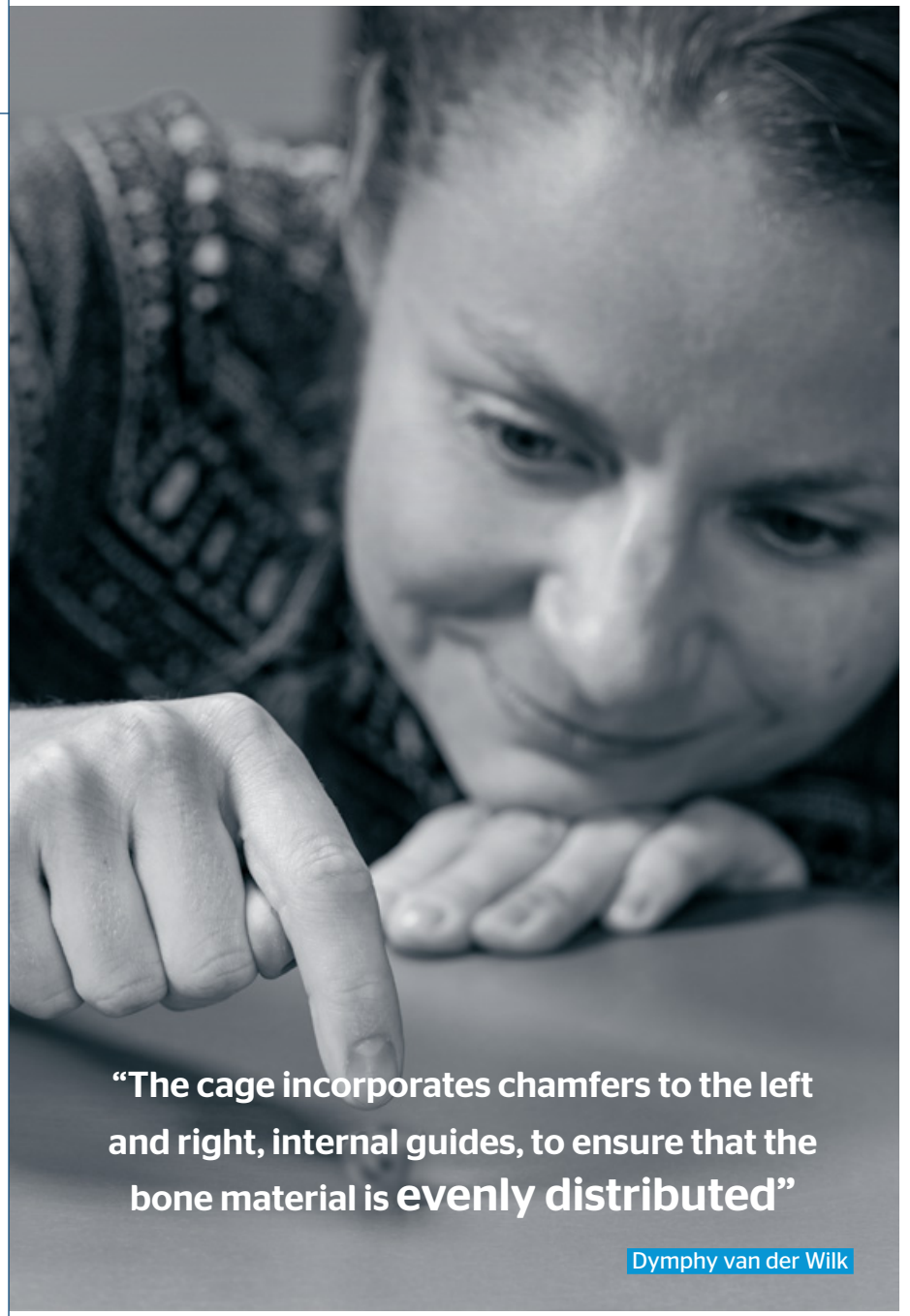
MANY INNOVATIVE PRODUCT IDEAS STEM FROM BOTH MINOR AND SIGNIFICANT FRUSTRATIONS. Jeff Kleiner, an orthopedic spinal surgeon until 2015 and an entrepreneur since 2013 in Denver, Colorado, found himself increasingly dissatisfied with the options available for minimally invasive spinal fusion procedures. These surgeries address issues for patients with damaged intervertebral discs, particularly in the lower back. A small implant, filled and encased with bone material, replaces the intervertebral disc, enabling the fusion of the upper and lower vertebrae.

Kleiner points out the shortcomings of existing devices: “The existing devices, which included a kind of extended funnel for delivering bone graft, had problems like jamming and underfilling the disc space, which often resulted in failed operations, where the vertebrae did not fuse properly.” Such failures severely impact the patient’s recovery and incur substantial healthcare costs; a surgical revision for a failed fusion can exceed $135,000 in the United States.

To demonstrate his solution, Kleiner gestures first with his hands in a round shape and then shifts to a rectangular form. “Most sets utilize a round insertion system, but you can’t push much bone graft through a round device. With a rectangular funnel, you can increase the cross-sectional area by 300%, maximizing the use of the surgical space.” This design innovation, along with improved distribution of the bone graft material, aims to enhance surgical success rates. Two engineers from Kleiner’s team, Alan Burkholder and Greg Causey, played pivotal roles in solving key challenges, such as avoiding pinch points for bone graft and ensuring a strong, reliable connection between the implant and the insertion cannula during surgery. Their efforts were tested and validated by BAAT.

THE COLLABORATION BEGAN DURING THE EUROSPINE MEETING IN 2018, where Kleiner and Causey were introduced to BAAT. Dymphy van der Wilk was a project engineer at BAAT at that time. “They approached us with the task of optimizing the design for a disposable set intended for cage insertion, ensuring controlled distribution of bone graft and suitability for FDA submission.” This partnership with the two American engineers yielded an instrument set featuring a funnel that seamlessly connects to an open-structured cage that acts as a conduit to support the delivery of graft. Van der Wilk elaborates: “The cage incorporates chamfers to the left and right, internal guides, to ensure that the bone material is evenly distributed.”

This project deviated from BAAT’s usual working methods, as the American engineers had already created initial designs. Van der Wilk explains: “We transformed their concept into a tangible product, though it was uncertain whether it would work as intended. We adapted their drawings into our system, incorporating necessary tolerances and dimensions. Our system enables us to conduct a structured review to ensure all information is accurate and complete.



The ‘revision management’ feature tracks any changes made to the design, allowing us to review the rationale behind our decisions. This level of structuring — often referred to as design control — was essential for FDA submission.”

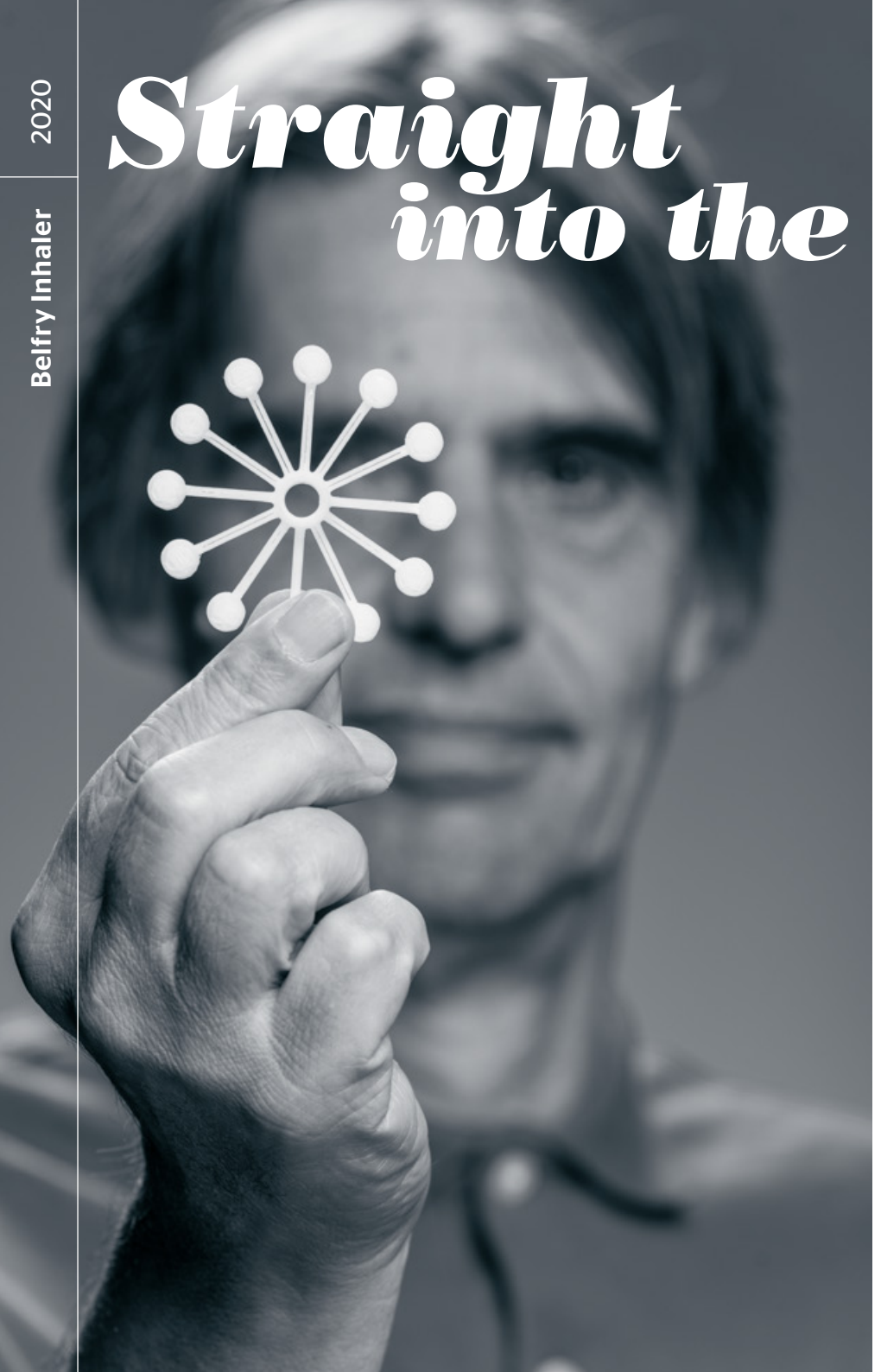
KLEINER REFLECTS POSITIVELY ON THIS COLLABORATION: “We lacked experience with single-use patient trays and were uncertain about the challenges we might face. And we didn’t know which hurdles to anticipate. BAAT did. I am grateful to say and hope I’m not cursing myself by doing this, but there hasn’t been a single request for a change in our system, no complaints from customers concerning things integrating or falling apart or doing anything beyond what we want it to do. It’s very much a win for us, and I think that BAAT and their oversight has a lot to do with that.”

BAAT also helped Kleiner’s team to navigate through complex regulatory processes. “With BAAT as ‘a manufacturer of records’ I got the same high-quality assurance program that big companies like Zimmer Biomet or Medtronic have, but with a more modest budget.” To date, the disposable instrument set has benefited the first 150 patients, marking a crucial milestone toward realizing Kleiner’s vision of significantly enhancing spinal surgery outcomes. He smiles, stating, “The next step is reaching 15,000 patients.” To achieve this goal, he aims to advance the U.S. market with the cost-effective single-use design of the KG2, starting with ambulatory surgery centers and rural hospitals.

What is typically BAAT?

Vincent Cloostermans:

"What makes BAAT special is the people. Everyone here is passionate and genuinely committed to developing a great product. They're opinionated in a good way and unafraid to speak up, even if their opinion might not be the one you want to hear. For a team where everyone feels free to weigh in on any topic they have insights on, there can't be rigid hierarchies. So, at BAAT, there aren't any. Whether you're talking to the director or an engineer, you're always welcome to share your thoughts."



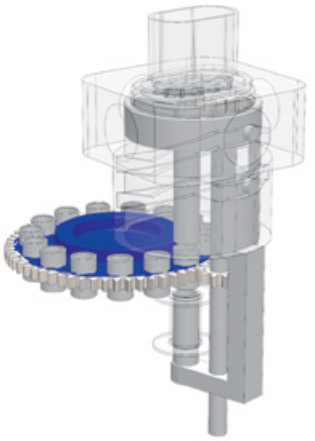
Straight into the blood-stream

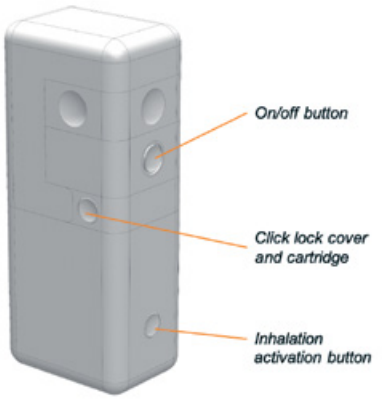
Precise micro-dosing of medicinal drugs via inhaler

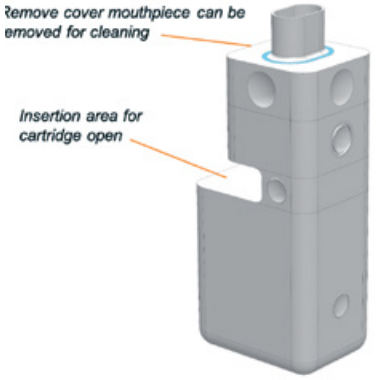
LONG-TIME RESIDENT OF GERMANY, PABLO ENRIQUEZ ORIGINALLY HAILS FROM ECUADOR. In 2018, the Founder and Director of Belfry Medical flew back to his family for the first time in five years. “There, I discovered that my grandfather, my role model, had become addicted to sleeping pills. He was just a shadow of the man who once dined in the White House with the President of the United States. His addiction made me very angry.” A common cause of developing an addiction to medicinal drugs is that it’s complicated to administer the correct dosage of the medicine. Sometimes, a body absorbs very little. Doses are increased to make sure that even in these cases, patients get enough, ‘just to be on the safe side’. Addiction becomes a potential risk.

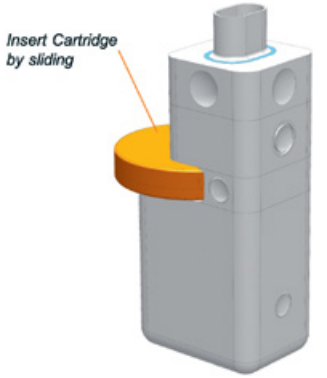
“Precision dosage, adjusted to each person’s absorption capacity, is the solution”, says Enriquez. To do this, he first studied how the body best absorbs medicinal drugs. It turned out that inhalation was the best of the three options: “Injecting yourself is a bit too extreme for many patients, and ingesting under the tongue is not as effective. In the latter case, the drug also goes to other parts of the body,

Product: ***Belfry Inhaler***
Customer: ***Belfry Medical, Berlin (DE)***
Part of the body: ***Entire body/lungs/blood circulation***
Start: ***2020***
Development: ***3 years***









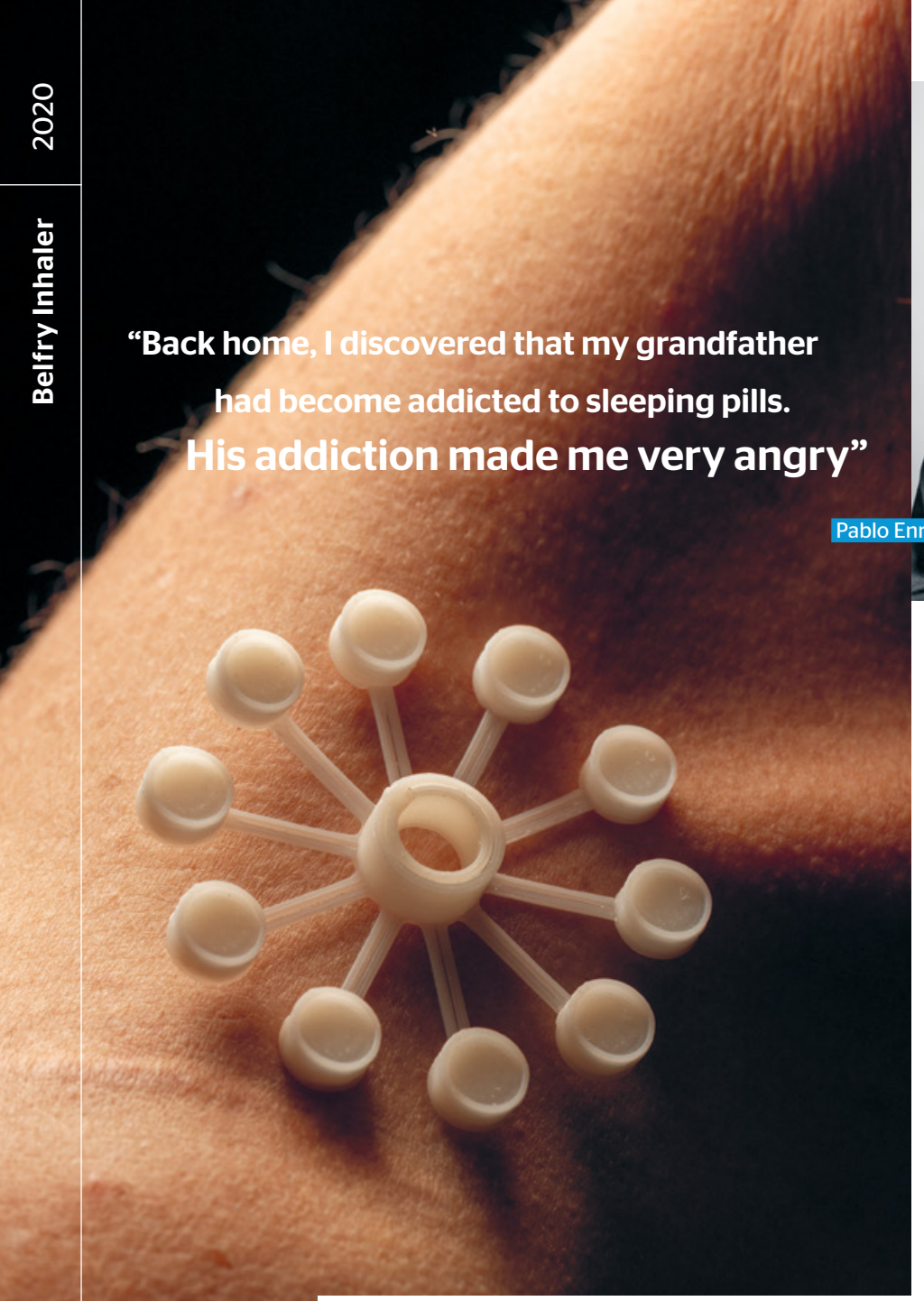
such as the stomach and liver. The Belfry Inhaler brings 100 percent of the medicinal drug into the bloodstream, allowing you to (micro)dose very precisely."

THE INHALER IS PAIRED WITH AN APP FOR PATIENTS that collects their data on usage and intake. This data enters the cloud, where the doctor can monitor it. "It allows the doctor to intervene quickly in case something is not right after all. The data also shows whether the treatment is effective and working." Finally, the inhaler also works out favorably for insurers: micro-dosing and monitoring mean that treatment for side effects is less frequent.

Armed with his innovative idea, Enriquez called on BAAT to develop it further together. This was a very complex job in terms of both technology and laws and regulations. "We first focused on existing technologies we could use for our inhaler, for example, from the tobacco industry. After almost a year of testing, we realized this was a dead end. We had to start developing the technology ourselves." This required more than in-depth knowledge about how the inhaler worked: "For example, you also need to know the chemistry of the heated substances." Regulatory compliance was equally challenging since the standards for a new type of medical device are very high. In short, there are many challenges, including financial ones. Martijn Heikens, project manager at BAAT, added: "Normally, a doctor or surgeon is the end user in our projects. Now, it is the patients themselves. This requires new considerations and measures regarding safe use."

MEANWHILE, IN TERMS OF DESIGN, THE PROJECT IS IN THE FINAL PHASE, and Enriquez feels that things will be faster and more streamlined from now on. "We are now focusing first on the inhalation of medicinal cannabis, also because patients face no significant health risks should something go wrong unexpectedly. From there, we want to slowly and responsibly spread our wings to other medicinal drugs."

Enriquez praises the cooperation with BAAT: "We have known each other for about ten years now. I feel at home



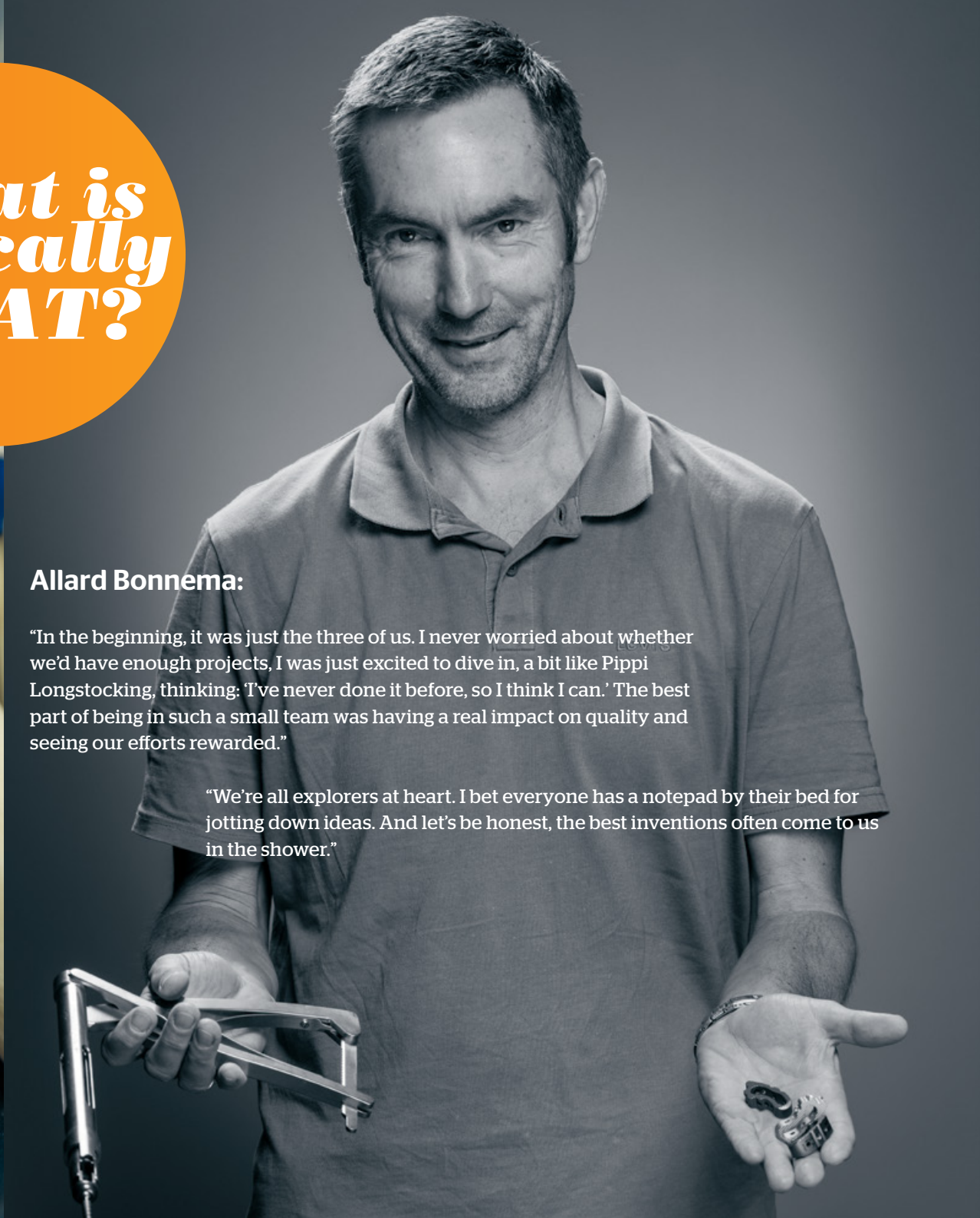
“Back home, I discovered that my grandfather had become addicted to sleeping pills. His addiction made me very angry”

Pablo Enriquez

when I visit Hengelo; I also know everyone there. We work together on very complex matters, treading uncharted paths. Sometimes opinions clash, and they are expressed to each other quite openly. I like that. And in the end, we have the same, common, higher goal: to help patients with a medical device.”

THE TERM ‘BUSINESS PARTNERS’ DOESN’T CAPTURE IT, Enriquez illustrates this with an anecdote: “Some time ago, I had the opportunity to present a venture to a potential customer in Barcelona. I felt I needed support with the technical details. I cautiously approached BAAT and asked if they could join me. That phone call was on Monday and by Tuesday, Arthur Aalsma and Vincent Cloostermans had already booked their flights. We presented together on Wednesday and flew back to our home countries on Thursday. It says a lot about them and the company ethos that they would rearrange their busy schedules especially to join me.

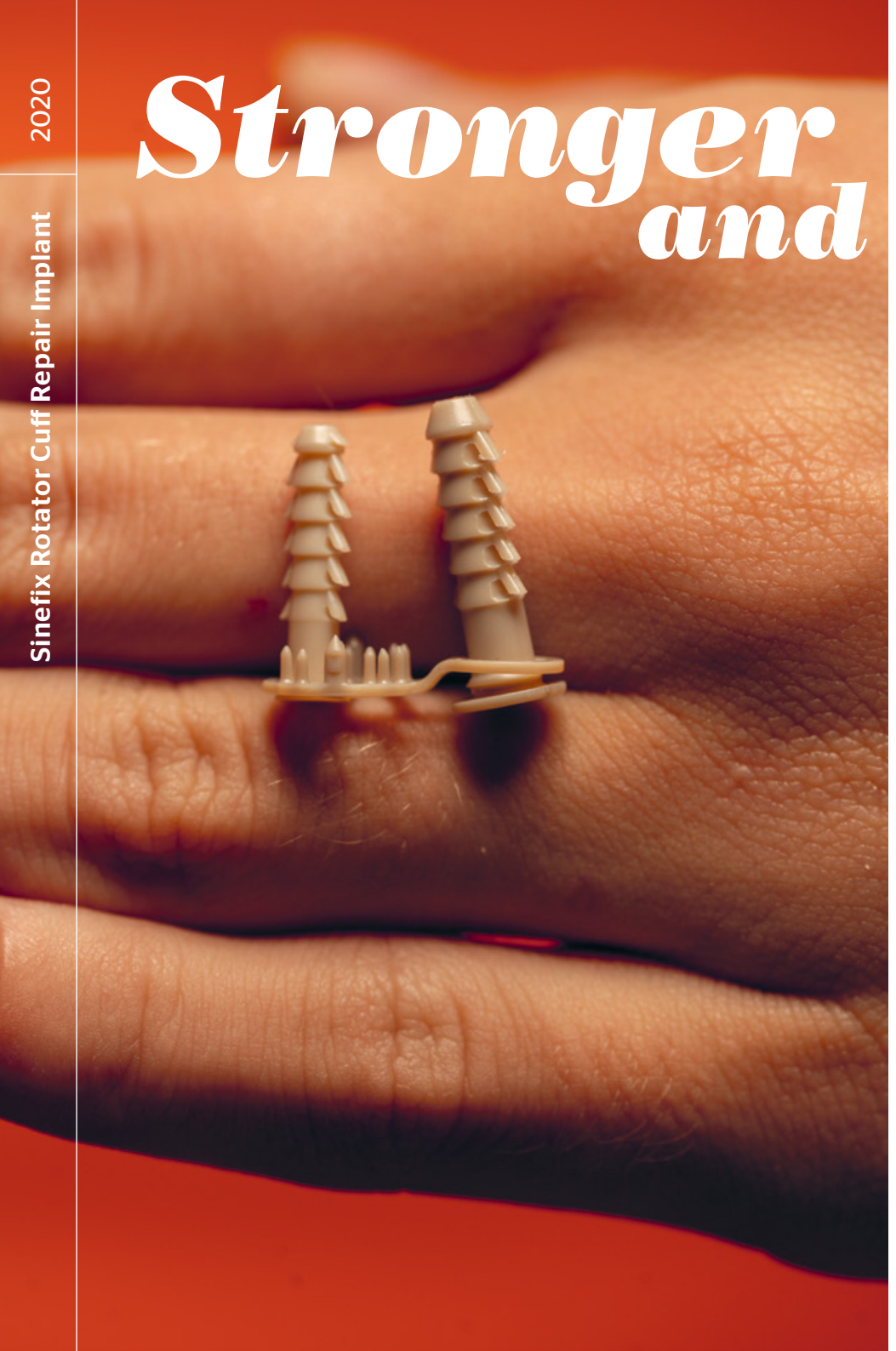
What is typically BAAT?



Allard Bonnema:

"In the beginning, it was just the three of us. I never worried about whether we'd have enough projects, I was just excited to dive in, a bit like Pippi Longstocking, thinking: 'I've never done it before, so I think I can.' The best part of being in such a small team was having a real impact on quality and seeing our efforts rewarded."

"We're all explorers at heart. I bet everyone has a notepad by their bed for jotting down ideas. And let's be honest, the best inventions often come to us in the shower."



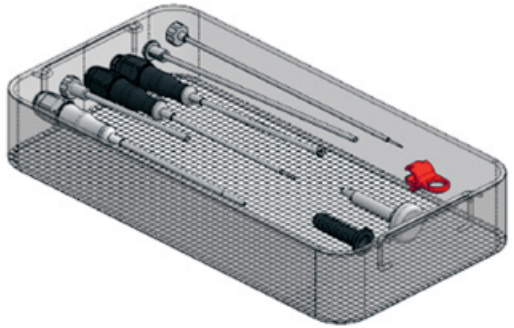
Stronger and less invasive

Better recovery from a tendon tear in the shoulder

THE ROTATOR CUFF CONSISTS OF THE FOUR DEEPER SHOULDER MUSCLES, the tendons surrounding the head of the shoulder like a cuff. When these rupture due to accident or injury, a complex surgery ensues with a relatively high risk of complications: In 20 to 70 percent of patients, a reattached tendon tears again. Surgeon Stefan Welte, working in the southern German town of Albstadt, went in search of a better alternative. For years, it was a recurring topic in conversations with Lukas Flöss, an entrepreneur in the metalworking industry. In 2019, they decided to make work of Welte's innovative ideas and founded Inovedis together.

"We had already made some designs that we had a good feeling about. Now we wanted to create a real prototype and develop it further under the applicable legislation", says Flöss. "For this, we sought contact with BAAT Medical." Torn shoulder tendons are usually reattached firmly to the bone with a conventional wire suture, Flöss explains. "We don't do that anymore. We use very thin polymer plates with small teeth on the underside. With much less pressure than traditional surgery, we thus pull the tendon over the shoulder head and anchor it firmly in the bone with a plastic anchor.

Product: ***Sinefix***
Customer: ***Inovedis, Eden Prairie (USA)***
Part of the body: ***Shoulder***
Start: ***2020***
Development: ***3 years***



"If something goes wrong with new technology, we'll have an army of lawyers on our doorstep in no time"

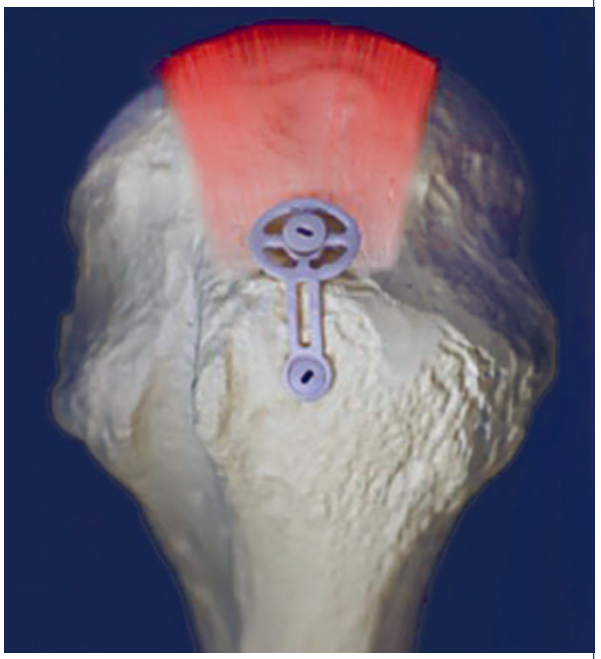
Lukas Flöss

Biomechanical research shows this construction is much stronger than the current standard." Johan Smits, project engineer at BAAT, adds: "Implanting the Sinefix is also minimally invasive."

BAAT HANDLED THE ENTIRE DEVELOPMENT PROCESS FOR THIS PROJECT. Smits: "The design existed, but we tinkered quite a bit in the initial phase. We changed the size of the anchors and made the instrument set, including a kind of screwdriver that you use to insert and secure the anchor." The results were good. The clinical trial started just recently, and there has been no detachment of the tendon. In addition to the implant, BAAT also designed the sterile packaging so that the surgeon can easily pick up the small parts without risk of contamination. "In cooperation with our suppliers, we chose a combination of already validated concepts that allowed us to reduce the development time drastically", Smits notes.

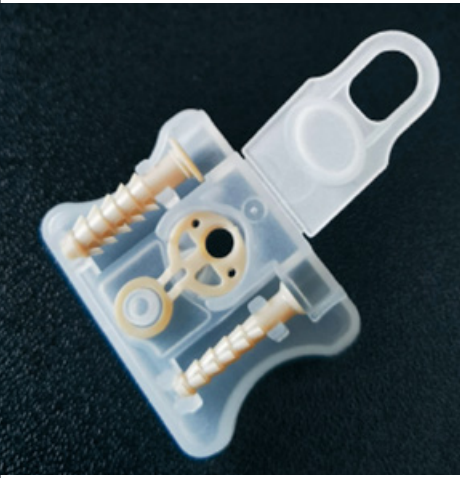
Smits often experiences customers having many ideas but can't choose what they want to develop first into a commercial product and bring to market: "Focus is essential for speed to market. For the Sinefix, we've decided to focus on small tears of two or three centimeters initially. Lukas and his team are already thinking about somewhat larger tears, but we agree that we will nail this first. In that respect, there is little interference or distraction of other ideas."

THAT FOCUS HAS LED TO THE SINEFIX BEING FDA-APPROVED FOR THE U.S. MARKET IN AN EXTREMELY SHORT TIME. Flöss: "Thanks to BAAT, this is a massive move for our company. Because it's so different, we have to explain our product in detail and prove its safety. If something goes wrong with new technology, we'll have an army of lawyers on our doorstep in no time." This is precisely why U.S. approval always poses a challenge. Smits believes: "While Inovedis rightly wants to profile itself with a highly innovative



“Focus is essential for speed to market. For the Sinefix, we’ve decided to focus on small tears of two or three centimeters initially”

Johan Smits

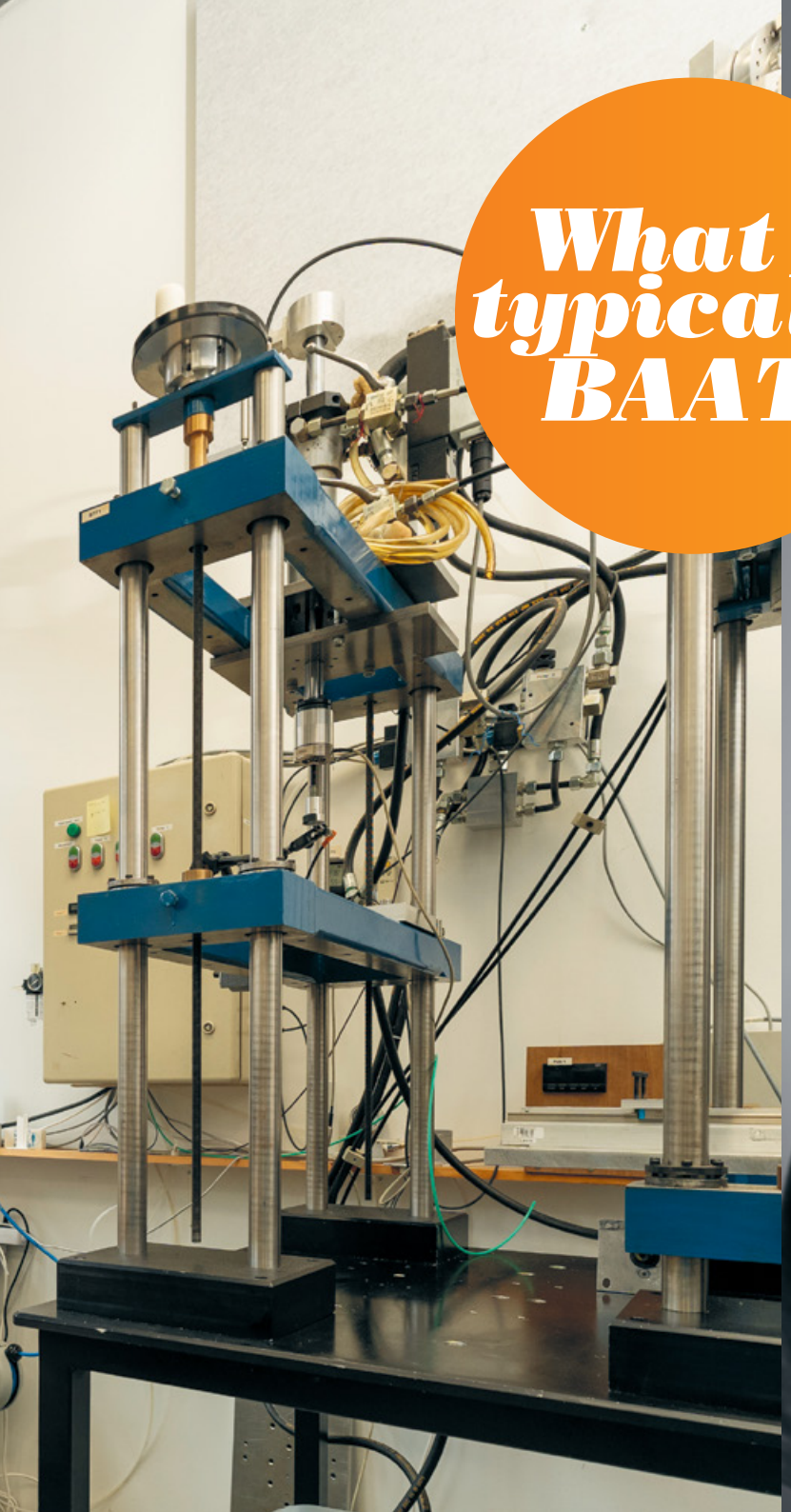


product, when it comes to the FDA, you want to substantiate your product as a composition of components that are already properly and safely recognized.”

The next milestone for Inovedis is obtaining CE marking in Europe. “That’s a longer process, which requires data collection”, Flöss says. “We aim to show that our method delivers superior results, which means we’ll need data from hundreds of patients.” A clinical study is underway in Tübingen, Germany, and a study is awaiting final approval at three other German clinics. Meanwhile, in the United States, the first patient has already been treated—a significant breakthrough that will allow us to build our business further”, he says.

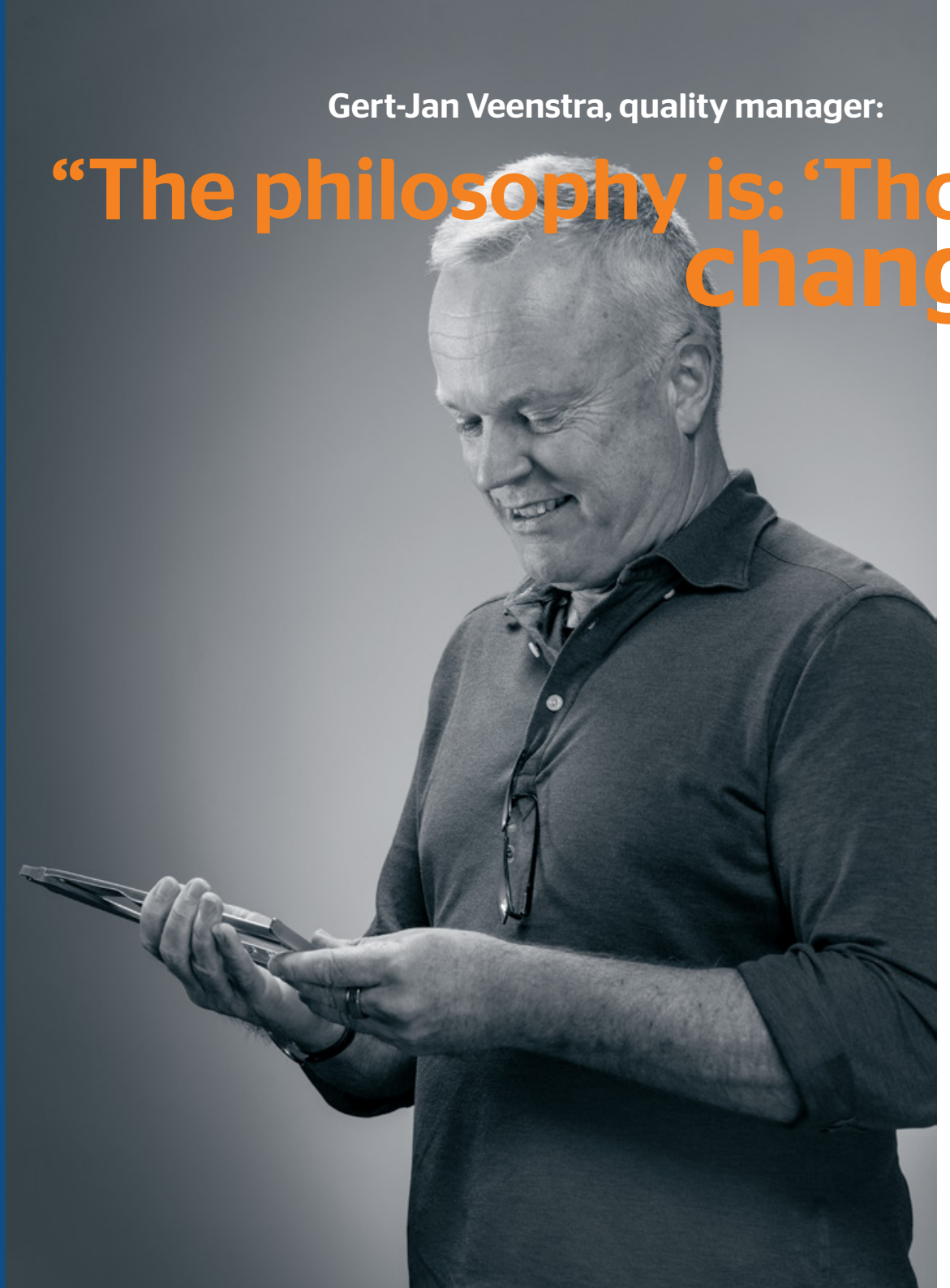
Inovedis also anticipates ongoing collaboration with BAAT, including the development of a new surgical technique for their product. Flöss describes the partnership as: “highly structured, with minimal deviation from the initial plan—a quality that appeals to our shareholders and investors, and to us even more.”

What is typically BAAT?



Huub ter Braak:

"At BAAT, we don't have our own products. When you finish a project, something new comes along. There's something new to work on every year. I personally rate medical products higher than everyday products. That's one of the reasons I'm still working at BAAT."



Gert-Jan Veenstra, quality manager:

“The philosophy is: ‘Thou shalt not change anything’”

THE FUN PART OF MY JOB IS TRANSLATING A FAIRLY ABSTRACT SYSTEM like an ISO standard or the MDR into something with which you can work as a company. You can do it very cleverly or very black and white, but in the latter case, it is difficult to work with. During the annual audits, a Notified Body comes to see how you have translated the rules of the law into your QMS and whether you are following your own system. One of those rules, for example, is that all suppliers of critical parts must be on an approved list. And to get on that list, the supplier has to comply with all kinds of rules. Which makes sense. Given the risk to the patient’s safety, we look at someone who supplies parts for an implant differently than someone who supplies office paper. So we do regular checks on these suppliers to make sure they really do what they say.

It’s not just the Notified Bodies that do the checking. We do it ourselves as well. Do the documents that are supplied comply with the regulations, are the products of the quality that we say they are? Are they of the material, dimensions, and strength that we have specified? We also check to see if they have been inspected by our operations department, for example.

If you want to sell a Medical Device in the European market, it must be CE-marked and therefore comply with the Medical Device Regulation (MDR). This requires a Quality Management System (QMS) that fulfills all requirements of the ISO 13485 standard. As Quality Manager, Gert-Jan Veenstra and his team are responsible for meeting these requirements.

AT THE MOMENT, IT IS EASIER TO GET A NEW PRODUCT APPROVED FOR THE AMERICAN MARKET than it is for the European market, especially if you are building on an existing technology that has already proven itself. However, the FDA is catching up in terms of stringency. As of 2026, their requirements will include ISO 13485. The medical market is very conservative. The philosophy is: 'Thou shalt not change anything'. If you want to bring innovative medical devices to the market, it's tough. You need deep pockets and a lot of time. Notified Bodies have hardly any experience with the MDR and are reluctant to release innovations for the market.

You can see now that the entire medical industry is still struggling with the most recent tightening of the law in 2017. At that time, the MDR replaced the old directive, the MDD. A large number of Notified Bodies stopped because of the demands the MDR also put on them. Now, if you're a startup and you want to get your product certified, it's hard to find a Notified Body that has time to do it. There are far fewer of them, and they are still in the process of reviewing all existing products that transit from MDD to MDR. You can also see some companies starting to phase out certain products because the effort to comply with the new regulations is no longer worth it. Fortunately, BAAT doesn't have to worry about that. We are prepared and helped many of our customers with the transition.

MANY COMPANIES ARE SECRETIVE ABOUT THEIR QUALITY SYSTEM. Not us. Six months ago, we started leasing our quality system to customers who outsource product development to us. The advantage for the customer is that they are working with a full-fledged system and that they are able to act as the legal manufacturer of the product that we are developing for them.

European Regulation

Medical devices are highly regulated. In 1993, six years before BAAT was founded, Europe introduced the Medical Device Directive (MDD) to ensure the safety and effectiveness of medical devices. In 2017, this regulation was tightened and replaced by the Medical Device Regulation (MDR), partly in response to some severe mishaps with medical devices like the breast implant scandal in 2010, in which a French company used cheaper industrial silicone instead of approved medical silicone, causing health problems for many women. Due to many reasons (e.g. COVID) the transition from MDD to MDR was postponed. Now all products must comply with the MDR before 2027. The new MDR requires developers to work in a structured manner, emphasizing risk management, clinical evaluation and traceability of products. BAAT's Quality and Regulatory team provides detailed guidelines to comply with European and American regulations and advises and controls during the development process to ensure that no steps are overlooked in our enthusiasm to develop innovative, safe and effective products.

Brianna Gerlach, quality systems engineer:

“We all have the same goal”

AS A QUALITY SYSTEMS ENGINEER, I WORK WITH THE QUALITY AND REGULATORY TEAM TO MAINTAIN OUR QUALITY MANAGEMENT SYSTEM. I make sure that our QMS documentation is up to date and aligned, and that people are trained on our processes. And I make sure our document management software is running smoothly. We started the transition to a new eQMS in April, and we still have a lot of documentation to upload, and we are improving it.

To be compliant, we need to show that everyone is properly trained and qualified for their job. So we are now investigating learning management system software to help us to offer, plan and track all training and have insight in the training status of all at any moment.

As a company in the medical device industry, there are rules and regulations that we have to follow. So we have to train, advise and help the team to comply. Sometimes we have to say: We cannot do it this way because of the regulations or because of our QMS, but we always try to find alternative solutions to achieve the best result. Although Quality may sometimes be perceived as an obstacle, everyone at BAAT (including Quality) has the same goal: We want to make an excellent and safe product.


BAAT
MEDICAL
BOS

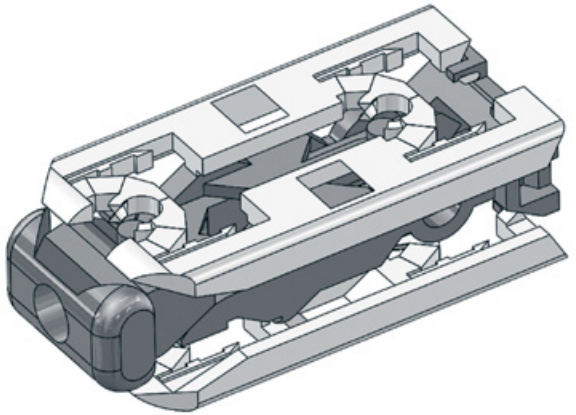
Minimal size, maximum functionality

Minimally invasive 3D printed expandable cages for intervertebral disc replacement

IT'S 5:30 IN THE MORNING ON A TUESDAY IN EARLY 2021. *In Tuttlingen, Germany — some 30 kilometers north of the Swiss border — Guntmar Eisen and a Blue Ocean Spine colleague get into a car. They make the same trip every two weeks: destination Hengelo, the Netherlands. "We usually arrived around noon, grabbed a quick meal, and then got straight to work with the team at BAAT Medical. We'd brainstorm, meet, and continue developing our product, the Blue Ocean Spine Expandable Cage", recalls Eisen. "By Wednesday afternoon around three, we'd drive back to make it home by midnight."*

Eisen's collaboration with BAAT began with previous projects, including the EIT CONDUIT porous titanium cages, a continuation of work with the Dutch company InSpine on 3D-printed interbody fusion cages for securing cervical and lumbar vertebrae. "With my previous company, Emerging Implant Technologies (EIT), we were the first to offer a complete portfolio of 3D-printed titanium cages for spinal fusion. What was unique was that I had only two engineers

Project: ***Blue Ocean Spine Expandable Cages***
Customer: ***Blue Ocean Spine, Tuttlingen (DE)***
Part of the body: ***Spine***
Start: ***2020***
Development: ***In final stage***



working on this, while BAAT supported with an entire team", he explains. In 2018, EIT was sold to Johnson & Johnson, and Eisen founded Blue Ocean Spine. By 2020, he was back collaborating with BAAT, this time focusing on multi-expandable cages.

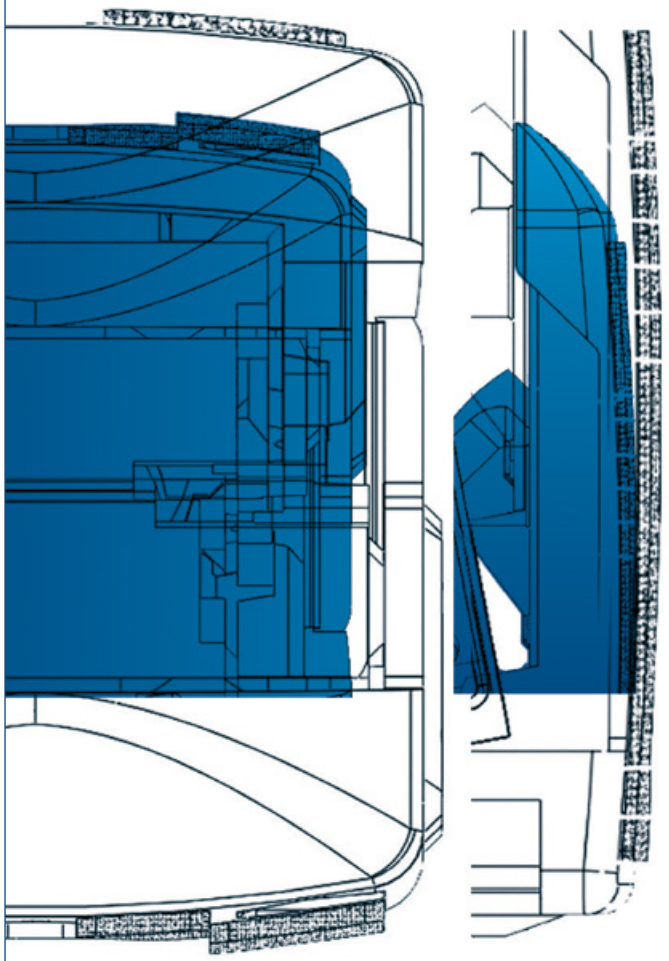
BACK IN THE EIT PERIOD, STATIC CAGES WERE THE INDUSTRY STANDARD. Hospitals had to stock 40-70 sizes to ensure a proper fit. "The downside was that the supplier only received payment for the specific cage used in surgery", says Eisen. On the other hand, expandable cages provide a significant advantage: they reduce the need for trial-and-error sizing in surgery, make the procedure less invasive for the patient, and reduce the number of sizes distributors need to carry. This results in a more precise fit with each patient's anatomy and greater efficiency.

"With the Blue Ocean Spine expandable cages, we wanted to go even further", explains Dorien Boiten, lead engineer for the BOS cages. "We designed them with independently adjustable height and angle adjustments. And we aimed to 3D print the product in a single run to eliminate the need for assembly." This approach enabled the production of a complex, multi-expandable cage at the price of a standard static cage: a significant economic advantage and a way to streamline inventory.

DESPITE THEIR ACCUMULATED EXPERTISE IN 3D PRINTING, Blue Ocean Spine and BAAT faced unexpected challenges with this new project. "Together with our 3D print supplier, we had to push the boundaries of what was technically possible at the time", Boiten explains. "Our main objectives were to print with very high accuracy, prevent any powder residue or unintended material sintering, and meet upwards of 100 quality requirements. We aimed to extract as much functionality as possible from minimal material." Even more challenging than the printing was inspecting the printed composite products. How can you inspect dimensions you can't access with conventional measuring tools?

The combination of minimal size and maximum functionality presented another critical challenge: "How can such a small component withstand the forces required?" Boiten says: "It has to support body weight while also being strong enough to separate vertebrae." This dilemma led to over a hundred design revisions, each adjusting every hundredth of a millimeter in pursuit of the final product. "Normally, a full design-production-test cycle

“The concept looked so promising on paper that we never lost faith”



Guntmar Eisen

would take three months, which we didn’t have. So, we collaborated with the engineering firm Reden to build a virtual testing environment. With simulations, we could quickly assess whether each design iteration met our mechanical strength requirements before physical testing. This process saved us months.”

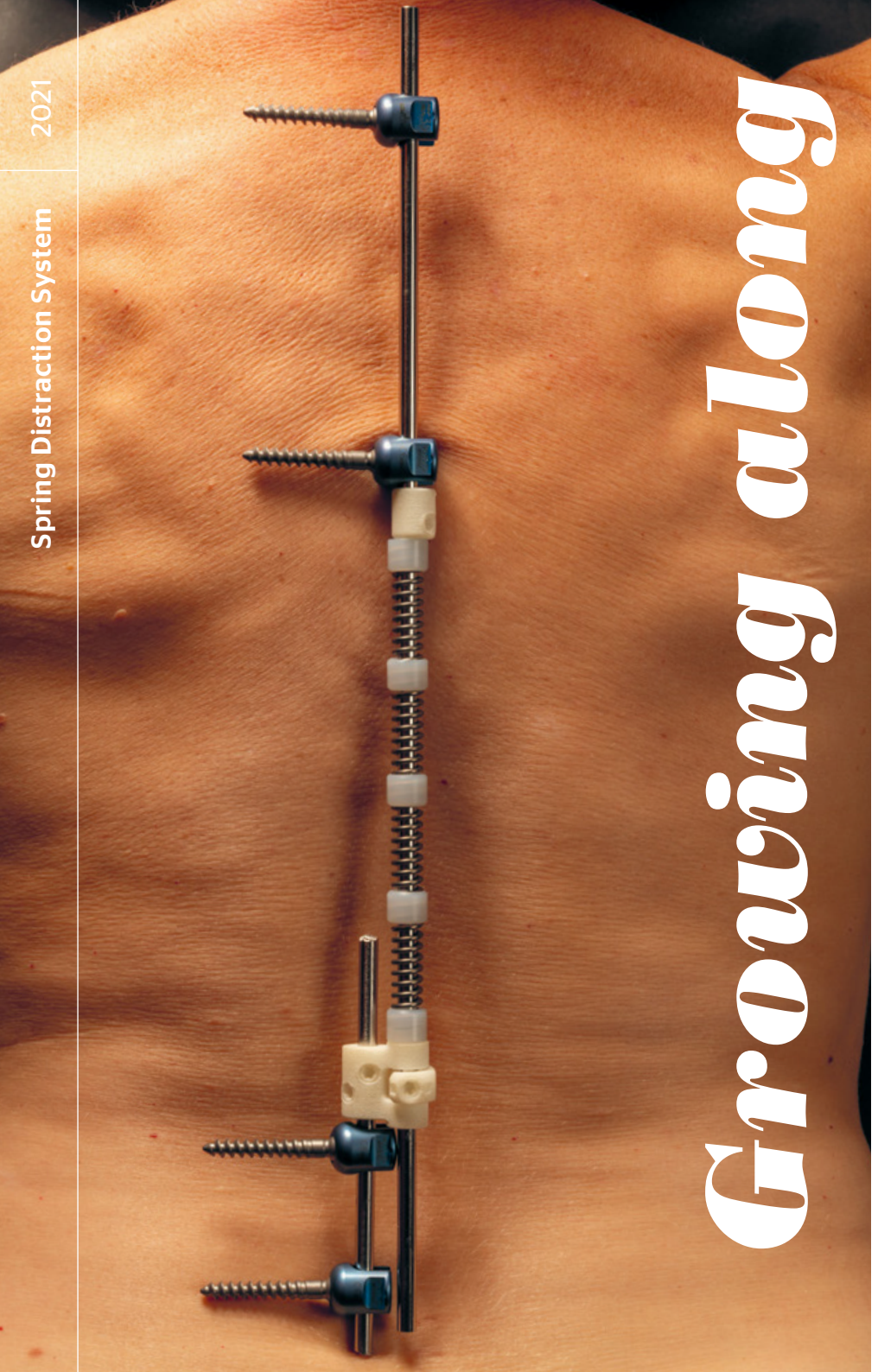
Investing thousands of hours without a guarantee of success was nerve-racking for Eisen. “But the concept looked so promising on paper that we never lost faith. Even at BAAT if they had to wait a while for invoice payment”, he adds. The mutual trust is now paying off; the products have passed mechanical testing, and development is complete. Eisen is optimistic: “We’re focused on validation tests and preparing for series production. We’re confident we’ll meet FDA regulations, and by the end of 2025, we hope to launch the product on the U.S. market.”

What is typically BAAT?

Simon Stevers

"As a relatively small company, we're very flexible. We can really get specific and tailor things to what each client needs. We're not bogged down by the rigid routines big companies often have, where 'this is just how it's done.'

"A bit of BAAT's signature style is that we're a little stubborn. We take on just about anything and trust we'll figure it out. Sometimes we think: 'How will we tackle this one?' Or we end up with designs in a place we hadn't planned for... but we always find a way through."



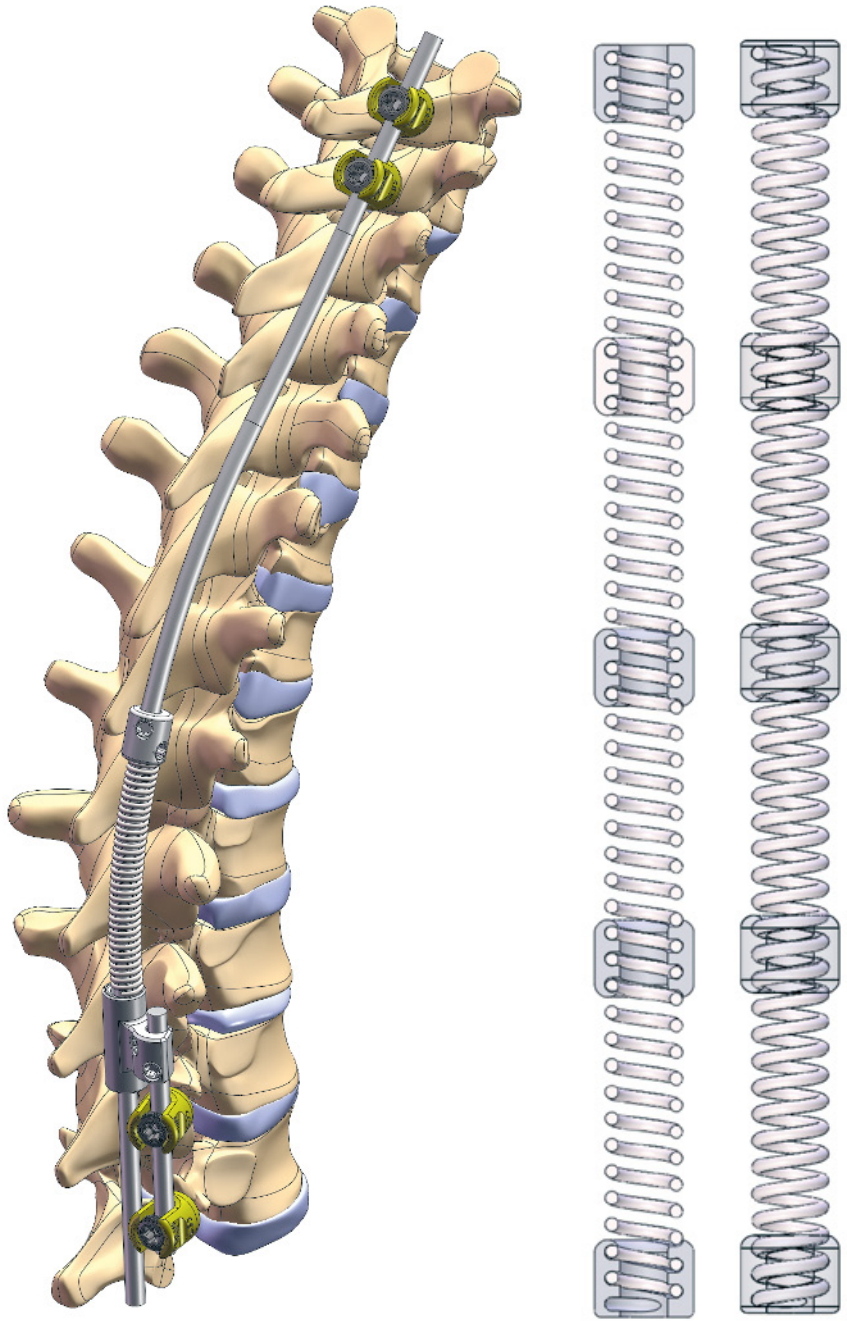
Growing along into adulthood

Aligning the spine to allow natural growth

IN UTRECHT, ORTHOPEDIC SURGEONS René Castelein and Moyo Kruyt had long been exploring better ways to treat children who develop scoliosis due to muscle disease. For these children with a spinal deformity, fixing their back is ultimately the best solution. But that's only an option when they're fully grown. Until that time — until maturity — they would have to undergo operations every three to four months to correct the spine to the desired position. That's not an option, of course.

The two surgeons developed the Spring Distraction System, a spinal rod that 'grows' with the children and corrects their spine internally continuously. This is done utilizing a spring, which slides over a 20 to 35 centimeter long rod, depending on a child's age and height. "They combined several existing techniques to create their construction and successfully implanted this 'growing rod' in 140 patients", says Dennis Magermans, director of Innovations at InSpine, a distributor in spinal implants. "The first patient from 2015 still has the implant in her back, and as an adult now, she's told us she is not bothered by it at all and has no desire to undergo surgery to remove it."

Product: ***Spring Distraction System***
Customer: ***Cresco Spine, Schiedam (NL)***
Part of the body: ***Spine***
Start: ***2021***
Development: ***In progress***



MAGERMANS BRIEFLY DETOURS to emphasize the importance of the Spring Distraction System, which should not be underestimated. “Most orthopedic conditions are said not to be life-threatening, and treatment only aims at improving quality of life. That’s true, except for progressive scoliosis. If your spine keeps deforming as it does with progressive scoliosis, your heart and lungs can become compromised, and that could lead to a life-threatening situation.”

Castelein and Kruyt took their invention to international conferences and were showered with praise. Magermans: “This created the unusual situation in which the market showed a lot of interest beforehand.” Vittorio Ricca, BAAT Medical’s project manager for this project since early 2023: “Rightly so, this an exciting innovation that the world and certainly patients are eagerly awaiting.” The two doctors gladly answered this call and asked InSpine to help.

THE COMPANY CRESCO SPINE WAS FOUNDED FOR THIS PRODUCT: “As a combination of existing products, the original growing rod was still far from ideal. There was room for improvement to the implant, so I contacted BAAT. Because of their expertise, but also because of their knowledge of the laws, regulations, and compliance with market access.” In this case, the American market. BAAT also checked whether the functionalities were correct, whether it could be made, and whether there were suppliers who could make it.


Vittorio Ricca

“Is a certain test really required, or can we use the budget elsewhere? We have heated discussions about that”


Dennis Magermans

“BAAT, among other things, adjusted the design so that the issue of wear of certain components — which did not fully match together — was solved.”

Both surgeons reacted with surprise to the requirements for a product like this, especially regarding laws and regulations. Ricca explains: “We know all the requirements for market entry. Surgeons sometimes view that as a waste of time. Castelein and Kruyt want to start operating with the improved version of their Spring Distraction System as soon as possible. I get that they must find it weird that another study with animals is required while they have already operated successfully on more than a hundred people.” Meanwhile, the Spring Distraction System is expected to get the green light from the FDA for the US market before the end of 2025. “The United States has labeled the system a breakthrough device designation”, Ricca adds. “It’s a special status aimed at speeding up approval and emphasizing urgency.”

LOOKING BACK AT THE PROJECT, Magermans says Cresco Spine was able to collaborate with BAAT very nicely. In this project, BAAT was mainly a facilitator, cleverly enhancing the ideas of Castelein and Kruyt. “As a commercial company, we sometimes think differently about addressing risks. Is a certain test really required, or can we use the budget elsewhere? We then have heated discussions about that.“ Ricca: “In the partnership with Cresco Spine, I feel the sense of freedom to be completely transparent and honest, which means we can make informed choices together about those risks.” Magermans points out they have already started another collaboration with BAAT: “That says it all, I think.”

What is typically BAAT?

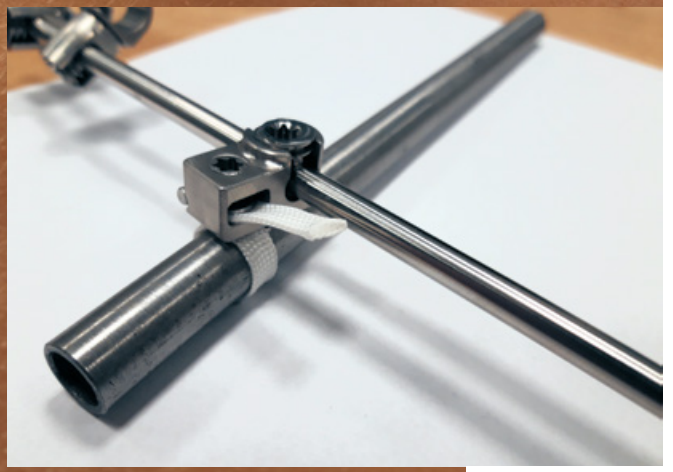
Juliette Slob

“The vibe and the open culture make working at BAAT enjoyable. Quite literally, no one has their own office, so you can easily reach out to anyone, including the executives.

BAAT also offers plenty of opportunities for growth. There are work-related courses you can take, and when you start, you’re paired with a buddy who helps you settle in, answers questions, and shows you the ropes. We have subject matter groups that hold lunch lectures to share their expertise. As a quality specialist, I still have a long list of topics I want to dive deeper into, so there’s no shortage of ways to grow and develop.”

A Meccano kit on your back

Correction of severe spinal deformities



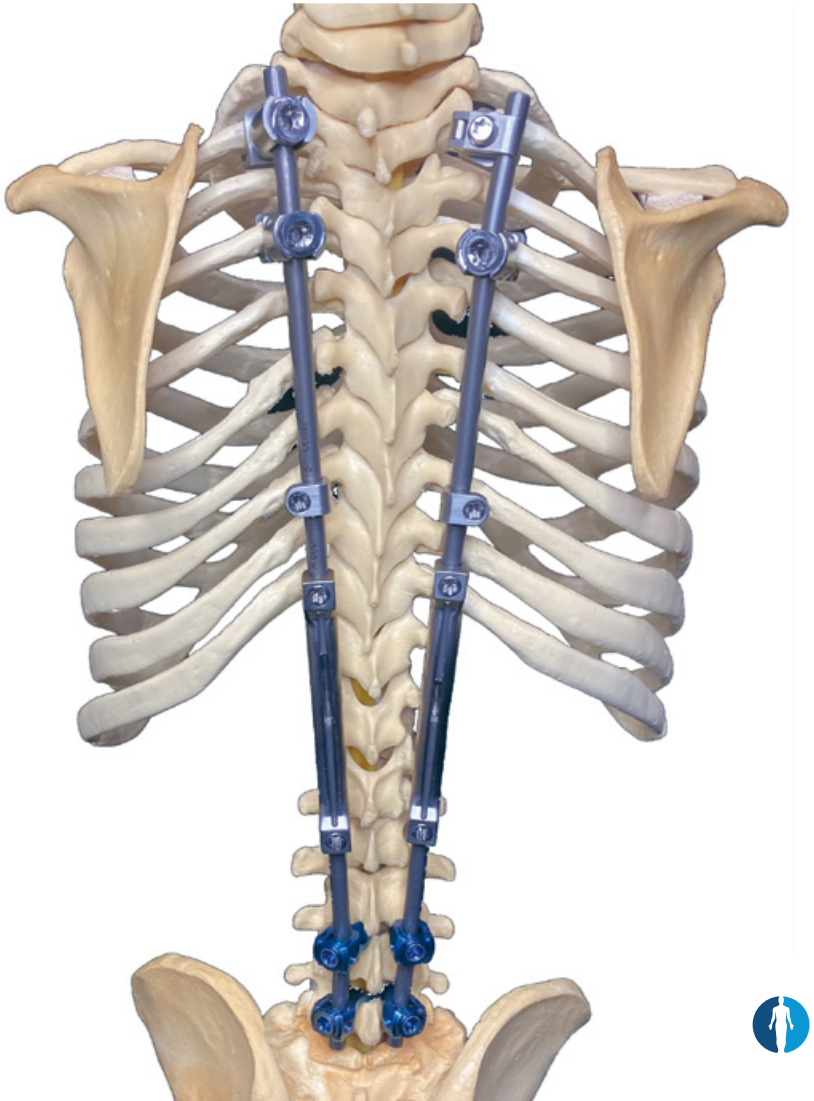
DANIEL BONTHIUS IS A RESEARCHER AND PHYSICIAN BASED AT A UNIVERSITY HOSPITAL in South Carolina. He founded Apex Orthopedic Technologies to address the complex needs of a specific patient group: children with severe congenital spinal deformities or Early-Onset Spinal Deformity (EOSD). He aims to improve these young patients' quality of life by stabilizing their spines with minimal surgical intervention. "Children who develop severe spinal deformities at very young ages tend to be medically fragile and face high complication rates", Bonthius explains. "Corrective surgery often requires multiple lengthening and revision procedures over time due to high complication rates and the nature of their condition. At Apex, we are developing a less invasive technique using rib fixation instead of traditional spinal fixation to correct EOSD. This technique is designed to lower complication rates, preserve spinal growth, and maximize functional outcomes." He named this solution the APEX R-FIX system.

BAAT Designer Timo Roubos, who collaborated on the project, was impressed with Bonthius' approach. "The system

Product: ***Apex R-FIX System***
Customer: ***Apex Orthopaedic Technologies, Mount Pleasant (US)***
Part of the body: ***Back***
Start: ***2022***
Development: ***2 years***

“Children who develop severe spinal deformities at very young ages tend to be medically fragile and face high complication rates”

Daniel Bonthius



resembles a Meccano set, with titanium rods designed to stabilize the vertebrae”, he says. Bonthius introduced an inventive method for fixation as well. “These patients often suffer from osteoporosis, making traditional screws unsuitable for securely fixing the R-FIX system to their vertebrae”, Roubos explains. “Bonthius proposed securing the structure with hooks around the vertebrae and ribs, providing significantly better stability.” Initial tests with existing hooks showed promising results, though there was room for improvement. “That’s why he asked us to design a hook specifically tailored to this application”, says Roubos. “We developed several prototypes, which Bonthius tested in cadaver lab sessions.”

THIS PROJECT WAS A UNIQUE EXPERIENCE FOR ROUBOS, as it was one of his first opportunities to design something from scratch. Weekly online meetings allowed the team to share progress with Bonthius. “These sessions were always open and honest”, Roubos recalls. “We presented our ideas through schematic 3D models created in SolidWorks, and Bonthius would give feedback on what could be improved. This back-and-forth helped us refine the designs, making them more precise and detailed each time.”

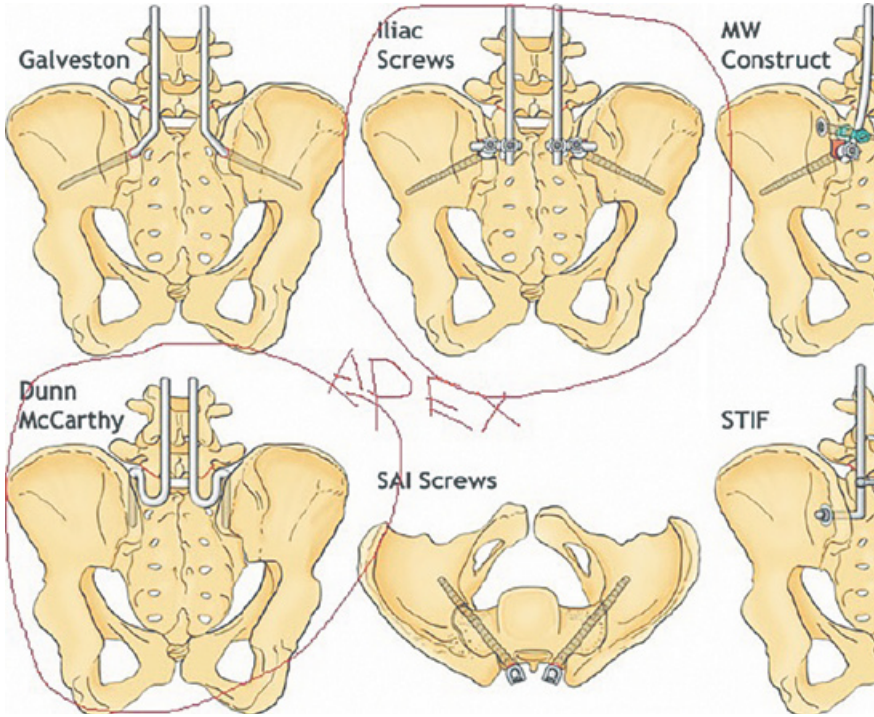
Timo Roubos

Helping People Get Better

BAAT is Roubos' first employer after his studies, which included a minor in Medical Device Technology in Dublin. "I was immediately drawn to medical engineering. Mechanical engineering can sometimes feel a bit detached because you're always working with machines. But medical engineering involves creating something that literally and figuratively helps people get better, and that combination really speaks to me."

Friday Afternoon Drinks

Timo Roubos said the informal tone of consultations with Bonthius matched BAAT's work culture. "We have informal Friday afternoon drinks, table tennis tournaments, and it's okay to be lighthearted in meetings", he says. "It's a relaxed environment, but that doesn't mean we don't work hard. Because BAAT is relatively small and has a flat organizational structure, you can explore various facets of medical device development. In larger companies, you often stick to your assigned tasks. But here, you can explore different areas and discover where your strengths and interests lie. For this project, our team was mostly designers, allowing us to divide the design tasks and let our creativity flow."

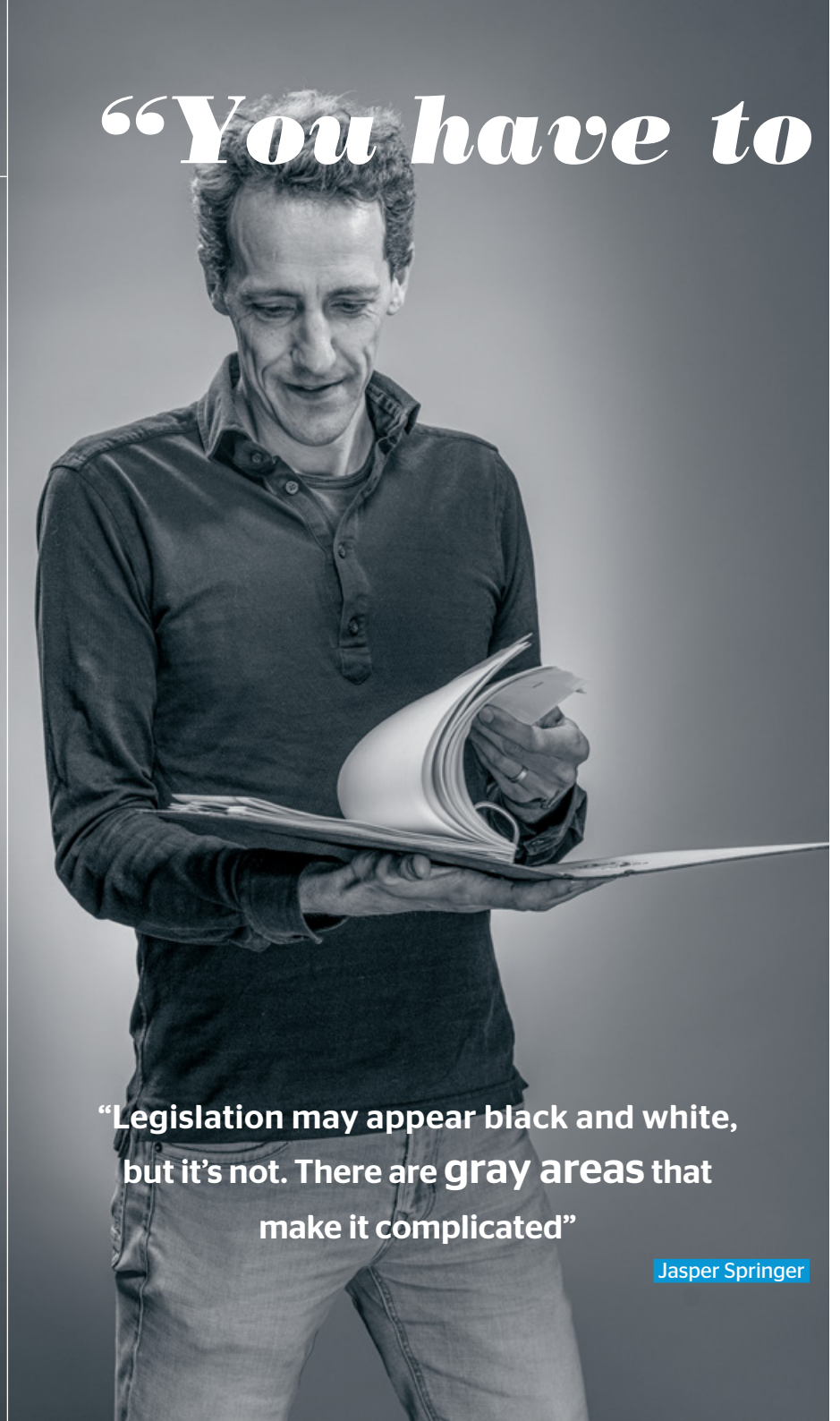


What is typically BAAT?

Bernic van der Spek:

"I really value the fact that we make medical devices. Medical technology has always interested me, and it's part of my background. I don't think other products are unimportant, but helping people, even in a small way, feels especially meaningful. We focus on developing products that we genuinely believe in, rather than being driven solely by profit."

"I think one of the best things about BAAT is that we keep it low-key. While CEOs at other companies might show off their fancy cars, Arthur and Gert have a friendly competition to see who can arrive at the office in the cheapest car."



“You have to substantiate all your claims”

Advising on end-user information

AS THE DEVELOPER OF INNOVATIVE SPRAY NOZZLES, MEDSPRAY PRODUCES THE TRACHOSPRAY, AMONG OTHERS. The trachea can be anesthetized via the mouth with precision, making it easier for doctors to intubate a patient. “Medspray is fully committed to developing cutting-edge technology”, says Jasper Springer, Regulatory Affairs Officer at BAAT Medical. While Trachospray was already on the market, the 2021 Medical Devices Regulation (MDR) Act required updates to consumer information to meet new compliance standards accordingly in the shorter term.

To navigate these new requirements, Medspray turned to BAAT Medical to review and advise on the updates needed. “The MDR is complex, and it can feel overwhelming if you are unfamiliar with it”, Jasper knows. BAAT has specialized in these regulations, often seen as an ‘afterthought’- allowing clients to leave it in capable hands. “We know which symbols to use and which paragraphs are required regardless”, Jasper explains. “Legislation may appear black and white, but it’s not. There are gray areas that make it complicated.”

Product: ***Regulatory Support Trachospray***
Customer: ***Medspray, Enschede (NL)***
Part of the body: ***—***
Start: ***2024***
Development: ***2 months***

"We know the rules of the game by heart when it comes to laws and regulatory affairs. We can, therefore, be that extra pair of eyes, a sounding board"

FOR INSTANCE, WORDS MATTER WHEN MAKING CLAIMS LIKE 'IMPROVED' OR 'NEW FORMULA' or comparing a product to a standard therapy. Jasper elaborates, "If the standard therapy changes, that claim might need to be adjusted. You have to verify that your claims hold up continually." Claims are always subject to rules anyway. "BAAT's approach ensures that data can substantiate every claim, such as stating that Trachospray numbs the trachea in a specific area. If you can't support a statement with data, it has no place in consumer information."

Medspray recognized some gaps in their end-user information, and BAAT's review process helped identify them. "We certainly found areas for improvement", Jasper recalls. "Our job was to lay out in our report what Medspray could do to close those gaps." Beyond regulatory requirements, other entities, from patients to competitors, scrutinize product claims. Jasper notes. "If one company claims something a competitor can't or hasn't, it impacts the market position. Competitors won't let unsubstantiated claims pass without challenge, which can lead to legal action."

THE JOB WAS DONE AFTER BAAT PRESENTED THE REPORT, and Medspray could act on the recommendations. "Medspray was very satisfied with the report. But ultimately, how they choose to implement our advice is up to them. They could support a desired claim with clinical data or decide to adjust it based on time or cost considerations. We know the rules of the game by heart when it comes to laws and regulatory affairs, and we know what's required and how to apply it in each specific case. Startups and other companies in the industry often don't. We can, therefore, be that extra pair of eyes, a sounding board."

In the future, BAAT plans to do this kind of short-term project in which BAAT acts primarily as a consultant more frequently. Jasper: "A report like this that we write for Medspray can open doors for future collaborations and new business opportunities."

BAAT staff over the years

Agustin Martin
Alexandros Savvidis
Allard Bonnema
Angelique van Leeuwen
Archana Yadav
Arthur Aalsma
Belal Rafik
Bernic van der Spek
Bettina Gerlach
Brianna Gerlach
Brigitte Janssen
Caroline Ingelaat
Chris Weed
Christos Michael
Cindy Rikhof
Danielle Van der Kouwe
Daphne Gengler
Dorien Boiten
Dymphy van der Wilk
Eliane Aychoua
Emma Sombroek
Emma van den Berg
Erik Huizing
Etienne Rutting
Frank Torma
Gary Antonius
Gert Nijenbanning
Gert-Jan Veenstra
Ghinwa Karkes
Harry Christenhusz
Harry Huizeling
Hugo Buijse
Huub ter Braak
Jasper Springer
Jeroen Cozijnsen
Jeroen Kunst
Jeroen van Gelder
Johan Smits
Jordi Borst
Juliëtte Slob
Kelsey van Abbema
Laurens Kamman
Lieke Tibben-Kuipers
Liesbeth Hols
Lisan Morsinkhof
Maaike Blankestijn
Maarten Pijper
Marc van Gorp
Marijke Hofstede-de Vries
Marnix Steenbeek
Martijn Heikens
Maurice Tak
Max Mosterd
Melanie Hubers
Monique van de Bergh
Odmar Christiaanse
Patrick Kleijnen
Patrick Pierik
Philip Ahmadyar
Rakhi Manik
Renate Herink
Rianne Bulsink
Rienk Jille Bijma
Rienk Zorgdrager
Rob Wielens
Roelof van Zwol
Ruben Godeschalk
Ryan D'Souza
Ryelle Endert-De Wit
Sander Verheul
Sean Farrugia
Sergio Posocco
Simon Stevers
Sterre Triezenberg
Tania Sharkey
Teake Bulstra
Tess Jimenez-Van Dam
Thomas van Blijswijk
Timo Roubos
Tom te Stroete
Usman Malik
Vincent Cloostermans
Vittorio Ricca
Ward Verschuur

Colophon

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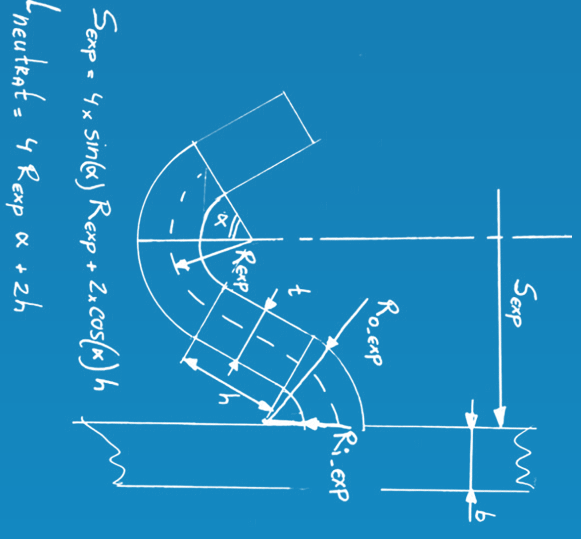
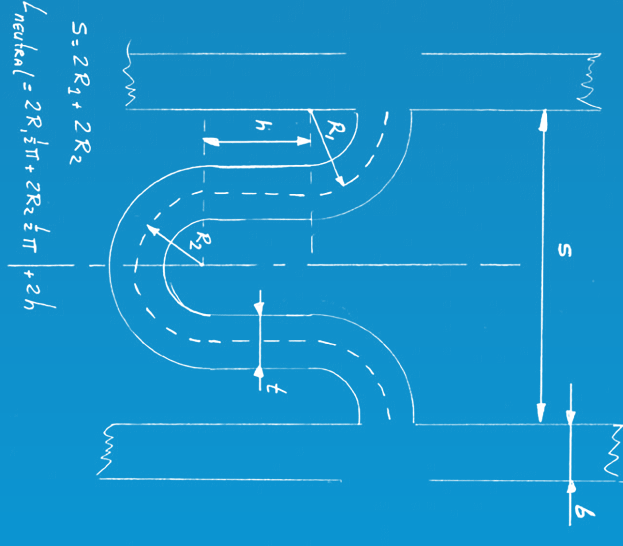
And a very special thanks to coordinator Teake Bulstra.
Without you this book would have been just another book.

2007
Nitinol Connectors
Biopsy Instrument
Spinal Pedicle Probe
Hip Implant Instruments
Minimally Invasive Posterior Cervical Fixation Instruments
Spinal Fixation
Custom Surgical Instruments
Anterior Spinal Fixation Instruments
Spinal Disc Nucleus Replacement
Interbody Preparation Device
Syphon Handle
Cervical Cage Instrument Set
Minimally Invasive Femoral Head Resection Tool
Wound Dressing Applicator
2008
Scoliosis Orthosis Plus
Ankle Fixation Implant
Thumb Orthosis
Minimally Invasive Interbody Fusion Device
Vertebral Cage Portfolio
Soft Tissue Staple System
Ergonomic Surgical Handles
Percutaneous Vertebral Body Augmentation Instrument Set
Radial Head Inserter
Iliac Screw
Rehabilitation Robot
Minimally Invasive Vertebral Jack Tool
Adjustable Soliosis Correction System
Re-usable Nitinol Scoliosis Correction Instrument
Spinal Clamping Device for Navigated Surgery
2009
Flexible Spinal Cage
Thoracic Sternum Brace
Dynamic Posterior Spinal Fixation System
Spinal Cord Nerve Connector
Anterior Spinal Disc Inserter
Patella Surgical Instruments
Knee Brace
Segmented Scoliosis System
Vertebral Body Replacement
Short Stem Hip Prosthesis
Universal Reposition Instrument
Cage Screw System
Spine Jack
Ankle Orthosis
Thoracal Lumbar Interbody Fusion Device
Lavage System
Hand Orthosis
2010
Lumbar Back Brace
Ankle Foot Orthosis
Polyaxial Pedicle Screw System
Femoral Head Reinforcement Implant
Foot and Ankle Stabilizer
Hip Brace
Posterior Spinal Fixation Instruments
Knee Orthosis
Clinical Evaluation Total Knee Replacement
Parallel Rod Connector
Coronary Staple Applicator
Redesign Re-usable Cervical Surgical Instruments
Cardiac Valve Repair Set
2011
Pediatric Scoliosis Correction System
Total Hip Replacement
Dynamic Hip Orthosis
Ankle Brace
Custom Spinal Hook System
Small Rod and Coupler
Surgical Instruments for Shoulder Implant Procedure
Re-usable Spinal Instruments
Sterile Packaging Spinal Implants
Dual Blade Scalpel for Cosmetic Surgery
Clavicle Fracture Pin
Customized Implants
Very Large Polyaxial Pedicle Screw
Cross Connector Spinal System
Calibration Instruments
Ankle Orthosis
Curved Rods for Spinal System
2012
Surgical Instruments
Minimally Invasive Distractor
Adjustable Intramedullary Nail
Disposable Aiming Instrument for Hip Arthroplasty
Interim Prosthesis
Custom Spinal Rod Inserter
Redesign Re-usable Spinal Surgical Instruments
Acetabulum Reamer
Kyphoplasty Implant
Adjustable Foot Adaptor for Lower Limb Prosthesis
Inflatable Surgery Cushion
Ankle Hinge Orthosis
Disposable Lavage System
Spinal Disc Replacement System
Re-usable Spinal Rod Benders
Custom Surgical Screw Driver
3D Printed Interbody Fusion Devices
Spinal Cage
3D Printing Process Validation
Shoulder Implant
Design Spinal Pediatric Adjustable System
510k Spinal Implants
Sternotomy Sutures
510k Osseointegrated Devices
Design Knee Extractor 2nd Gen.
Suture Knot Pusher
Humerus Fracture Plate System
2022
Tennis Elbow Treatment Device
Nerve Growth Inhibition Device
Cranial Implants
Dynamic Cervical Cage
Disposable Trocar
Vascular Repair System
Minimally Invasive Cervical Cage and Instruments
2023
Spinal Cages
Knee Extraction System
Ankle Nail
UV Disinfector
Surgical Instrument Pedicle Preparation
Tubular Bandage
Growing Rod Spring Distraction System
Cranial Plate System
Compression Screw
Spinal Kyphosis Correction System
Medical App
Washer Cap
Disinfection System
Rotator Cuff Repair System 2nd Gen.
Custom Made Implant
Micro Needle Blood Collection Device
Spinal Cages and Surgical Instruments
Surgical Drill
2024
Ecto Dermal Neuro Stimulation Suite
Smart Prosthetic Knee Joint
Anesthetic Spray Device MDD to MDR
Anesthetic Spray Device 510k
Spinal Implants MDD to MDR
Spinal Implants FDA
Shoulder Implant Design Upgrade
Innovation Scan Respiration Analysis System
Rotator Cuff Repair Implant 2nd Gen.
Bone Graft Preparation Instrument
Medical Navigation Instruments
Minimally Invasive Adapter
Cement Stop Hip Implant Procedure
Surgical Instrument Set Rotator Cuff Implant
Surgical Instruments for Navigated Surgery
Magnesium Based Resorbable Implants
Micro Needle System
Shoulder Implant Extended Instrument Set



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