Are You Ready for Robots?

How Robotics and Automation Are Transforming Processes and Productivity for Medical Device Design Engineers

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Introduction

Advances in materials science, 3D printing, rapid prototyping, software/hardware convergence, software democratization, big data and cloud computing are creating a profound shift in medical device design and manufacturing.

Key among the advances reshaping the thinking of medical device design engineers?

Automation and robotics – two areas expected to surge as labor costs rise around the globe and mass customization becomes the norm.[1]

Even traditionally labor-intensive industries like footwear and apparel are adopting more robotic automation, altering product designs to utilize no-sew, bonded fabrics that are more automation friendly.

Are "robotics and automation" the same thing? For the purpose of this paper, yes. Both are forms of "industrial automation" versus "software automation." According to a recent blog by Robotiq[12], "robotics and automation" involve using physical machines and control systems to automate tasks within an industrial process. A CNC machine is a form of industrial automation; so, too, is a robot. But there is a difference. Robots are reprogrammable machines that interact with the physical world via sensors and actuators to carry out a series of actions autonomously, or semi-autonomously.

Traditional industrial robots are typically big, strong devices requiring fences and guards for human safety. Collaborative robots, or cobots, are lightweight and dexterous robots designed to work safely along side humans. Both are flexible ways to automate a task or process in the physical, not virtual, world.

- So what's current state in robotics use for medical device design and manufacture?
- How are robotics and automation transforming processes key to long-term productivity and profitability?
- What do end users think of robotics use in medical devices?
- Where are robotics headed?
- And what can medical device designers do now to prepare for the brave new world that lies ahead?
- While the robotics story is still evolving, here's what we see happening today.

Robotics Use is Big - and Increasing Globally

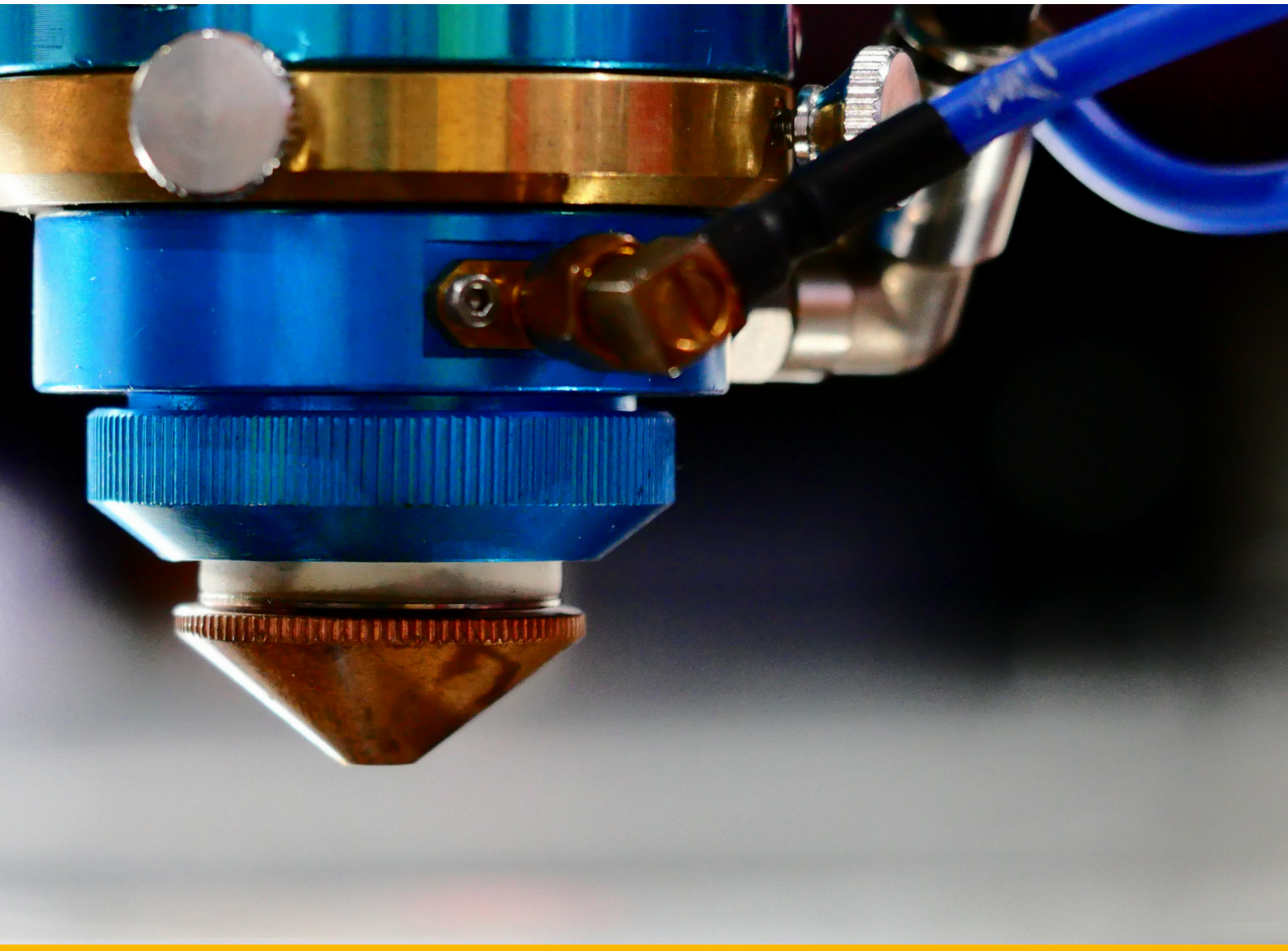
Research published by analyst firm Gartner has predicted that one in three jobs will be automated using robotics or software by 2025. A recent report from International Data Corporation reinforces these findings, claiming that the robot market is set to boom in the next three years, growing at a Compound Annual Growth Rate (CAGR) of 17%.[2]

What's more, a 2016 analysis of 752 of The Robot Report's global database of robotics-related startup companies shows that 25% of the startups were focused on industrial robotics, while 75% were exploring new robotics areas. Of the 75%, 7% -- more than fifty companies -- are involved in developing medical, surgical and rehabilitation robots[3].

What You Can Do Now:
These medical device startups might be worth connecting with, either for inspiration or possible business. To find them, use the internet as a source of information or reach out to venture capitalists involved in the startup community.

Here are two places to begin your search:

- **https://angel.co/health-care**
- **http://www.healthcareitnews.com/slideshow/healthcare-it-startups-watch-running-list-big-news-2017?page=1**



Robotics Use in Medical Devices: Current State

Whether for human healthcare in hospitals and clinics or laboratory analysis/drug discovery, robotics use in medical devices – defined by the FDA as "...an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or ... component part of accessory ... intended for use in the diagnosis of disease ... or in the cure, mitigation, treatment or prevention of disease" -- is on the rise in the life science universe.

In hospitals and clinics, demand for robotics in healthcare, especially surgical procedures, is increasing. Safety, better clinical outcomes, and reduced labor costs are leading to an exponential growth in demand not only for robotic-assisted surgery, but in many other segments of healthcare such as sanitation, sterilization, lab processing and materials handling. From radiation treatment to eye surgery, rehabilitation to hair transplantation, and robot therapists to robotic pharmacists, and even a robot phlebotomist, healthcare robots are transforming the fields of medicine across the globe.

Limited to economies that are heavily invested in medical care, growth in these facilities is seen to be exponential to 2020 and steady thereafter.[4] According to a recent report by Credence Research, the global medical robotics market was valued at $7.24 billion in 2015 and is expected to grow to $20 billion by 2023.[5]

Life science laboratories are also benefiting from the adoption of automation and robotics. That's according to Clifford Baron, director of marketing for global services and solutions at Applied Biosystems, in an article in Science Magazine. "What's driving acceptance of robotics is the fact that the cost of error is very high, in a scientific paper or developing a drug," says Baron. "Even fairly low error rates can have a profound impact on the conclusions you make downstream based on your data." Mike Olive, director of molecular biology at LI-COR Biosciences, develops that thought. "The average researcher in the lab needs consistent quality," he explains. "You assume that by taking out the human element you will get more consistency."[6]

Another emerging trend in lab automation is to fully automate drug discovery workflows through "robotic researchers" that apply advanced machine learning and artificial intelligence to streamline compound screening, hit validation and analysis.[7]

Realizing the benefits of robotics and automation – including greater consistency, growing customization, and the generation of more and more relevant and revealing data – doctors, hospital and clinic administrators, and lab and pharma PhDs are increasingly using and implementing robotics. If robotics is what your audience wants, then robotics and their benefits are what you deliver as medical device designers.

Given the necessary highest standards of medical device design and performance, the incredibly complicated business model of health care, and stiff regulatory requirements, that's anything but an easy task.

What You Can Do Now to Facilitate Robotics:
If you're looking to add automation and robotics to your operations – or further their contribution to your operations – an initial robotics "self-assessment" might be in order. Take a hard look at your design and manufacturing processes to identify repetitive, onerous or dangerous tasks currently done by humans that might be better done by robots. Explore what gains deploying robots could offer in productivity, efficiency and waste reduction. Are there processes that require high precision and dexterity for which human talent is increasingly scarce [8]?

Robotic Impact on Medical Device Design: Smarter, Faster

Robotics and automation have long been recognized for delivering speed, efficiency and productivity, particularly in manufacturing and assembly. But how will they help medical device designers meet the growing need for flexibility and adaptability to fast-changing customer needs, bringing new products to market faster? One way is through design for automation, or DFX where "X" stands for automation.

As OEMs spend more time evaluating the factors that drive total cost, they're encouraging medical device designers to explore the possibilities of automation in the early stages of product design. They want to align product development with automation strategies that cut time to commercialization by minimizing design iteration and/or tooling design revisions, maximizing production and assembly[9].

Working on design for automation up front is vital in medical devices because of the approval process involved. Once regulatory go-ahead is secured, it can be difficult to go back and make even minor modifications to a design, whether to reduce changeovers or any other purpose.[1]

Derek Pietz, president of Silicon Valley's L2F, a robotics integrator, believes the biggest advantage of design for automation is time to market. "Time to market of a new product, a new innovation, a new company, that's what is critical. By looking at automation early on, you can maybe skip some development steps. You can maybe prove out some level of pilot development that will let you iterate your product more effectively. And maybe even skip some automation steps that you won't need later. You can have that initial ramp and initial launch occur months, maybe years earlier because you successfully managed risk and your end user experience more effectively[1]."

Lightweight, off-the-shelf robotic systems for medical device integration through design for automation are already on the market. Functioning as a simple motion control platform, these robots can save significant development time. Designers don't have to spend years trying to figure out how to build and control the system; they just have to focus on creating the tool at the end of the robot and the interface for the customer[4].

Of course, designing medical device innovations using robotics is one thing. Bringing them to market cost effectively is another. No surprise, then, that robotics and automation are critical to achieving that goal as well.

What You Can Do Now to Further Robotics Design: Make sure your design engineers are well versed in design for automation. Choose one or two engineers in the group and invest in keeping them current in design for automation techniques. This will allow them to serve as internal DFX consultants when problems arise. Or alternately, connect with outside automation experts or system integrators. Bring them in early to work with device designers to build fixed automation -- or flexible automation with robots -- into the design stage.

Robotic Impact on Medical Device Produce-ability: Fostering Collaboration

As indicated above, the earlier design engineers start looking at the automated manufacturing process and how it affects a specific design, the better. Yet expertise in design does not necessarily translate into expertise in produce-ability, which is defined as the ease of manufacturing a product in economies of scale – in other words, the economical fabrication, assembly, and inspection or testing of a product in a volume manufacturing environment. As global competition to deliver products quickly and reliably increases, produce-ability with automation is a growing concern – one that fosters the need for collaboration between design engineers and automation experts, or even contract manufacturers.

Take Tegra Medical. In 2015, the medical device manufacturer was facing profit erosion as costs escalated and customers demanded price cuts. The company's solution? Deploying three collaborative robot arms. The automation doubled throughput, freed up 11 full-time positions and enabled the manufacturer to keep up with customer demand[10].

Using a mixed model cell feeding three different products simultaneously in the same machining cycle, the robots offered cost advantages, ease of implementation and ease of use. Best of all, they eliminated the need for additional qualifications and validation activities. By simply replacing the operator with the robot, the validated process remained unchanged; only the handling of components in-between the processes changed. The replaced operators were repurposed into other operations to keep up with company growth.

As design engineers continue to create increasingly complex designs, the importance of produce-ability grows. Products with miniaturization, articulation, complex geometries, advanced materials, electronics and wireless capabilities create challenges for assembly and automation.

According to "Finding Ways to Make Automation Automatic," an article on Medical Product Outsourcing's website, some of the most complex devices to manufacture are combination products, such as sophisticated drug delivery products that combine both the drug and the delivery system into one device. Julie Logothetis, president of Morristown, N.J.-based Kahle Automation, a global supplier of custom-built automation equipment for life science companies, comments on the complexity.

> *"This is extremely challenging as you cross from different levels of sterility and handle expensive, delicate components. Automation is required for these products because they cannot be manufactured any other way. There is no room for error – a product malfunction could result in serious injury, or even death to the user[9]."*

As the role of robotics and automation in produce-ability becomes increasingly important, the technology is continually innovating. For example:

- Robots are being used in innovative ways in medical device and laboratory assembly – i.e., part feeding, cells for high position accuracy, splicing, welding and labeling
- Robotics are becoming increasingly modular, facilitating custom-designed cells for specific product and volume runs, reducing product costs dramatically
- Robots are learning from environmental cues within their work spaces. Adapting to changes in their surroundings eliminates the need for reprogramming, increasing efficiency and saving time

What You Can Do Now to Grow Your Produce-ability Capabilities:
Assess the ROI of robotics compared to the cost of relying on human labor. Begin to build in-depth relationships with automation experts and system integrators who can help you maximize robotics and automation integration in medical device manufacturing. Work to leverage modular automation. Decide what level of automation suits your business: full automation or partial automation, where 'personal robotics' create a smaller work station type of environment[6].

Where Robotics is Headed

As robots become smarter, faster and cheaper, their roles in medical device design and manufacturing will continue to change as more "human" capabilities such as sensing, dexterity, memory and trainability are developed. While discussed where robots are headed is a little like reading tarot cards, here are a few robotics trends being discussed in life science literature:

- Increased usage of robots and automation will drive a systemic human resource change, creating the need for more human talent to train, repair and minister to the growing robotic workforce
- The rise of cheaper and more easily programmable robots will open the door to small-lots production and greater end user customization
- Machine-to-machine knowledge sharing will make it easier for companies to switch production from one location to another, or from the production of one product to another, without the considerable investments in talent, training, setup time and cost of traditional manufacturing
- Widespread automation will fully integrate computer artificial intelligence and robotics
- The use of mobile robots in service applications will continue to grow

Probably more than in any other industry, innovation is the lifeblood of life science. Robotics and automation are the cells and platelets of that blood, driving transformations that will redefine medical device design and manufacturing as we know it.

According to Katy George, McKinsey's expert in its operations practice and pharmaceutical and medical products, the impact of robotics, coupled with other advances like 3D printing and software/hardware democratization, will increasingly push the industry towards a design-for-value orientation, spurring greater cross-functional collaboration and integration of the marketing or commercial functions. "It's not just about cost reduction," George says. It's actually about continuing to evolve the product design the right way[11]."

If she's right that's good news for everyone in life sciences, from patient and physician to payor, regulator, pathologist and PhD.

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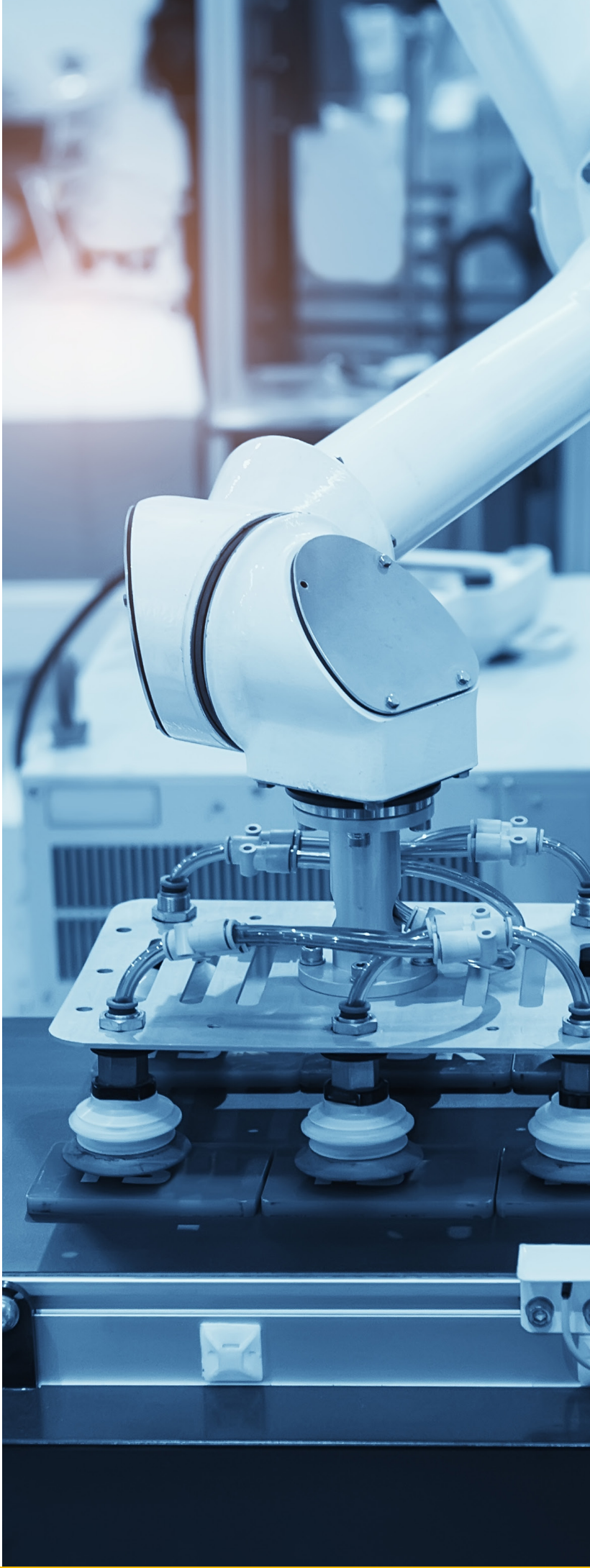

Parker Worldwide

Europe, Middle East, Africa

AE – United Arab Emirates,
Dubai
Tel: +971 4 8127100
parker.me@parker.com

AT – Austria, St. Florian
Tel: +43 (0)7224 66201
parker.austria@parker.com

AZ – Azerbaijan, Baku
Tel: +994 50 2233 458
parker.azerbaijan@parker.com

BE/NL/LU – Benelux,
Hendrik Ido Ambacht
Tel: +31 (0)541 585 000
parker.nl@parker.com

BG – Bulgaria, Sofia
Tel: +359 2 980 1344
parker.bulgaria@parker.com

BY – Belarus, Minsk
Tel: +48 (0)22 573 24 00
parker.poland@parker.com

CH – Switzerland, Etoy
Tel: +41 (0)21 821 87 00
parker.switzerland@parker.com

CZ – Czech Republic, Klecany
Tel: +420 284 083 111
parker.czechrepublic@parker.com

DE – Germany, Kaarst
Tel: +49 (0)2131 4016 0
parker.germany@parker.com

DK – Denmark, Ballerup
Tel: +45 43 56 04 00
parker.denmark@parker.com

ES – Spain, Madrid
Tel: +34 902 330 001
parker.spain@parker.com

FI – Finland, Vantaa
Tel: +358 (0)20 753 2500
parker.finland@parker.com

FR – France, Contamine s/Arve
Tel: +33 (0)4 50 25 80 25
parker.france@parker.com

GR – Greece, Piraeus
Tel: +30 210 933 6450
parker.greece@parker.com

HU – Hungary, Budaörs
Tel: +36 23 885 470
parker.hungary@parker.com

IE – Ireland, Dublin
Tel: +353 (0)1 466 6370
parker.ireland@parker.com

IL – Israel
Tel: +39 02 45 19 21
parker.israel@parker.com

IT – Italy, Corsico (MI)
Tel: +39 02 45 19 21
parker.italy@parker.com

KZ – Kazakhstan, Almaty
Tel: +7 7273 561 000
parker.easteurope@parker.com

NO – Norway, Asker
Tel: +47 66 75 34 00
parker.norway@parker.com

PL – Poland, Warsaw
Tel: +48 (0)22 573 24 00
parker.poland@parker.com

PT – Portugal
Tel: +351 22 999 7360
parker.portugal@parker.com

RO – Romania, Bucharest
Tel: +40 21 252 1382
parker.romania@parker.com

RU – Russia, Moscow
Tel: +7 495 645-2156
parker.russia@parker.com

SE – Sweden, Borås
Tel: +46 (0)8 59 79 50 00
parker.sweden@parker.com

SK – Slovakia, Banská Bystrica
Tel: +421 484 162 252
parker.slovakia@parker.com

SL – Slovenia, Novo Mesto
Tel: +386 7 337 6650
parker.slovenia@parker.com

TR – Turkey, Istanbul
Tel: +90 216 4997081
parker.turkey@parker.com

UA – Ukraine, Kiev
Tel: +48 (0)22 573 24 00
parker.poland@parker.com

UK – United Kingdom, Warwick
Tel: +44 (0)1926 317 878
parker.uk@parker.com

ZA – South Africa, Kempton Park
Tel: +27 (0)11 961 0700
parker.southafrica@parker.com

North America

CA – Canada, Milton, Ontario
Tel: +1 905 693 3000

US – USA, Cleveland
Tel: +1 216 896 3000

Asia Pacific

AU – Australia, Castle Hill
Tel: +61 (0)2-9634 7777

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