ProSpon

The Art of
Technical Surgery

CUSTOM-MADE REPLACEMENTS

PROSPON COMPANY HISTORY

1911 **Walter** company, later a renowned manufacturer of cars and aircraft engines, was established

1983 Walter Motorlet **Univerzál** – first knee prosthesis made in Czechoslovakia

Walter **Modulár** – a modular-type knee prosthesis **1997**

2012 MEDIN Orthopaedics **Vektor** – a modernised modular-type knee prosthesis

The company merged with ProSpon s. r. o. **2014**

2015

Technology of 3D-printed titanium and titanium-alloy prostheses

2014

MEDIN Orthopaedics, a. s. and ProSpon s. r. o. merged

2000

First ProSpon custom-made bone replacement implants

1993

Sosna – first ProSpon shoulder joint prosthesis

1992

ProSpon company established after the founders from Poldi Kladno left

PROSPON TECHNOLOGY

ProSpon is a company that develops, manufactures and distributes medical devices. ProSpon holds PROSPON TECHNOLOGY the IQNET, CQS, ISO 13485 and CE certificates covering the manufacture of class I, IIb and III implants.

Brief history and the present:

Founded in 1992, the company has been focusing on the development, manufacture and sale of medical devices for orthopaedics, traumatology and cancer therapy. Currently, the company concentrates on implants for the replacement of all major joints in orthopaedics and cancer therapy. The company also manufactures implants for small joint replacement, external fixators, instruments and implants for reconstruction of the anterior cruciate ligament, spinal fixators, custom-made implants and OEM products, as well as veterinary implants.

ProSpon products are used by 80% of clinical sites in the Czech Republic (e.g., ProSpon covers about 50% of the Czech market of external fixators). Each of the end customers, which are mainly state-owned hospitals, selects a specific structure from the company product portfolio. ProSpon also sells its products (including prostheses) in foreign markets, e.g. in Poland, Belarus, Russian Federation and Spain.

The company's strategy is to develop, manufacture, and distribute top quality and affordable medical devices. As a high-priority component, the company strategy includes research & development, including collaboration with the academic world, such as the Czech Technical University in Prague, University of Technology in Brno, Technical University of Ostrava, Prague Institute of Chemical Technology, Czech Academy of Sciences and the 1st Faculty of Medicine, Charles University in Prague. The vast majority of products manufactured by the company are designed in-house, and this is a strategy that the company wishes to pursue in the future as well. The results of completed company research projects are welcomed by the target markets. ProSpon is one of the founding members of Czechimplant.cz – an association of medical device manufacturers and academic workplaces, established in order to promote efficient cooperation among its members in the development and manufacture of products that will withstand rivalry in the harsh environment of the globalized market and ever-stricter European legislation.

Some of our products patented in 2015-2020:

- Equipment for combined osteosynthesis of comminuted fractures of the proximal segment of the ulna (2015, Patent No. 306140)
- Intracorporal sensor (2015, Utility Model No. 28204)
- Solution for the creation of active antibacterial nanolayers (2016, Utility Model No. 30507)
- Modular ankle-bone replacement implant for cancer patients (2017, Utility Model No. 31098)
- Metallic substrate with an electrostatically deposited bioactive collagen/calcium phosphate-based nano-composite support for antibiotics (2017, Utility Model No. 31357)
- Magnesium alloy for biodegradable implants (2017, Utility Model No. 31364)
- Antibacterial implant coating with a photocatalytic effect and the method for its creation on the implant surface (2018, Patent No. 307777)
- Cotyloid cavity (2018, Utility Model No. 32237)
- Non-cemented all-porous acetabular component (2019, Utility Model No. 32805)
- Full hallux metatarsophalangeal joint replacement implant (2020, Utility Model No. 34201)

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PROSPON TECHNOLOGY

ProSpon has an experienced design team that uses SOLIDWORKS 3D CAD software from Dassault Systèmes, including a PDM system for comprehensive management of electronic documents. X-ray and CT (as well as MRI) data are processed and converted into data compatible with computerized 3D models by using Mimics Innovation Suite software from Materialise. Custom-made bone replacement implant designs are continually discussed with doctors by using plastic implant models, typically made of PLA 3D material by printing using the Fused Filament Fabrication technique. This 3D print technology is also used to manufacture sterilisable, disposable instruments, targeters in particular. Such products are made of a special material for medical devices that meets the requirement for biocompatibility for short-term contact with human tissue according to ISO 10993-1. Where appropriate, the stress behaviour and load-bearing capacity of the future implant are examined by mathematical simulation (FEM). The implants, completed with a porous structure in appropriate points, are then manufactured mainly by using the additive method of 3D printing. The implant material is titanium alloy Ti6Al4V ELI and the technology is direct metal laser sintering on an M2 Cusing machine manufactured by Concept Laser. This fusion of technologies enables us to manufacture individualized implants. Moreover, the system can be extended with compatible modular ProSpon bone replacement implants from the company's serial manufacture segment. Post-processing uses conventional technologies / CNC machining centres to attain the required dimensional accuracy/precision, surface quality and mechanical properties (in particular, annealing to eliminate stresses, sometimes also isostatic hot pressing to reduce unwanted porosity in the material bulk). Special surface finishing, such as deposition of a hard diamond-like carbon (DLC) layer, colour anodizing or mineral hydroxyapatite spraying to support osteointegration, is outsourced to specialised institutions. In the development domain, ProSpon works on innovations in cooperation with the Academic World. This concerns, for instance, antibacterial coatings, smart endoprostheses, material surface strengthening by the action of an impact wave constituted by high-energy laser pulses, all of which may find application in the future. The development scientists and engineers follow the latest trends in the field and participate in international events such as congresses devoted to medical topics as well as general topics with impacts on the majority of technical areas, such as 3D printing and nanotechnologies.

Example of a custom-made implant. Left: physical model made of plastic by printing on a 3D printer after processing patient data and converting them to a 3D computer model. Right: the final (here: growing) paediatric knee joint implant with the replacement of a part of the femur.

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CUSTOM-MADE IMPLANTS: INTRODUCTION

Brief description:

Implants for cancer patients have been manufactured by ProSpon since 2000. Over 3500 implants have been used in patients to date. Of these, about 60% were knee joint replacement implants, 25% were hip joint replacement implants and the remaining 15% were implants for other joints and other bones. The proportion of fully custom-made products has been increasing.

The implants are made of the light-weight but strong titanium alloy, Ti6Al4V ELI (ISO 5832-3), coated with a DLC (diamond-like carbon) layer which (i) prevents what is called titanosis, a phenomenon that occurs when using uncoated titanium material, and (ii) exhibits excellent tribological properties. The sliding parts of the knee joint implant are made of a polymer referred to as PEEK (poly-ether-ether-ketone). Where friction pairs with a metal are involved, the polymer is filled with carbon fibres: this lightweight material is highly resistant both to friction and to mechanical stresses, thereby extending the implant service life. As a bonus, this material does not pose any problem during MR imaging, is transparent to electromagnetic radiation (X-rays) and can be sterilised by various methods. Owing to this material combination, ProSpon implants rank among unique products of this type on a worldwide scale.

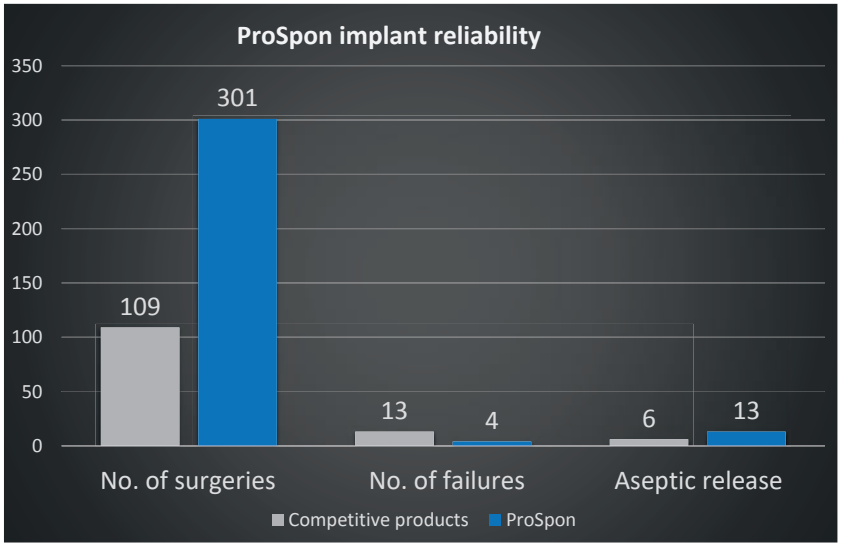
Custom-made (CM) implants are manufactured for specific patients:

a) either with the possibility of connection to certain series production parts (such as hip heads)

b) or as fully custom-made products

The ProSpon product range covers replacement implants for all large joints (knee, hip, shoulder, elbow, ankle and wrist), diaphyseal implants, pelvis, scapula, jaw, or for the total replacement of all long bones such as the hip-femur-knee-tibia-ankle system (see the overview overleaf). As for their reliability, ProSpon implants are among the top products worldwide. ProSpon implants for cancer patients fail very rarely, although they are implant types that are stressed much more than conventional orthopaedic bone replacement implants (large resections associated with higher bending forces,...)

Implant reliability comparison at a cancer clinic in Moscow:



CUSTOM-MADE IMPLANTS: OVERVIEW

GROWING PROXIMAL
HUMERUS REPLACEMENT

MODUL PROXIMAL
HUMERUS REPLACEMENT

ELBOW JOINT
REPLACEMENT

TOTAL
HUMERUS
REPLACEMENT

ELBOW JOINT
REPLACEMENT

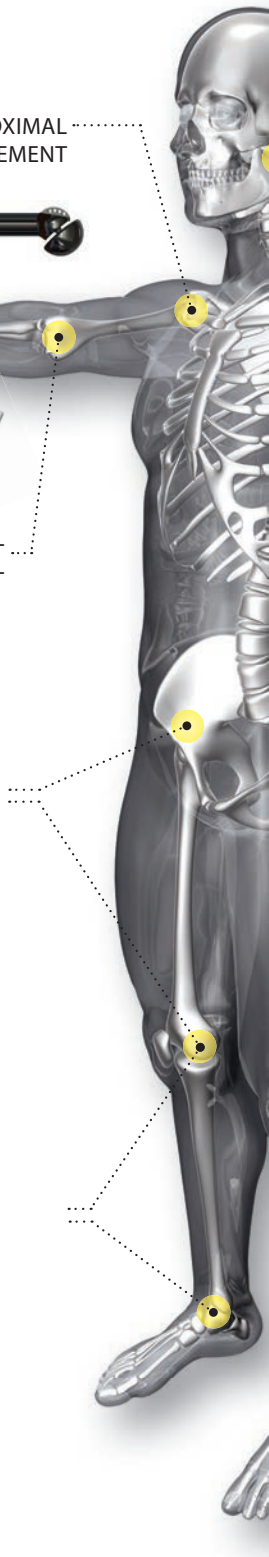
PELVIS REPLACEMENT
WITH COTYLOID CAVITY

TOTAL FEMUR
REPLACEMENT

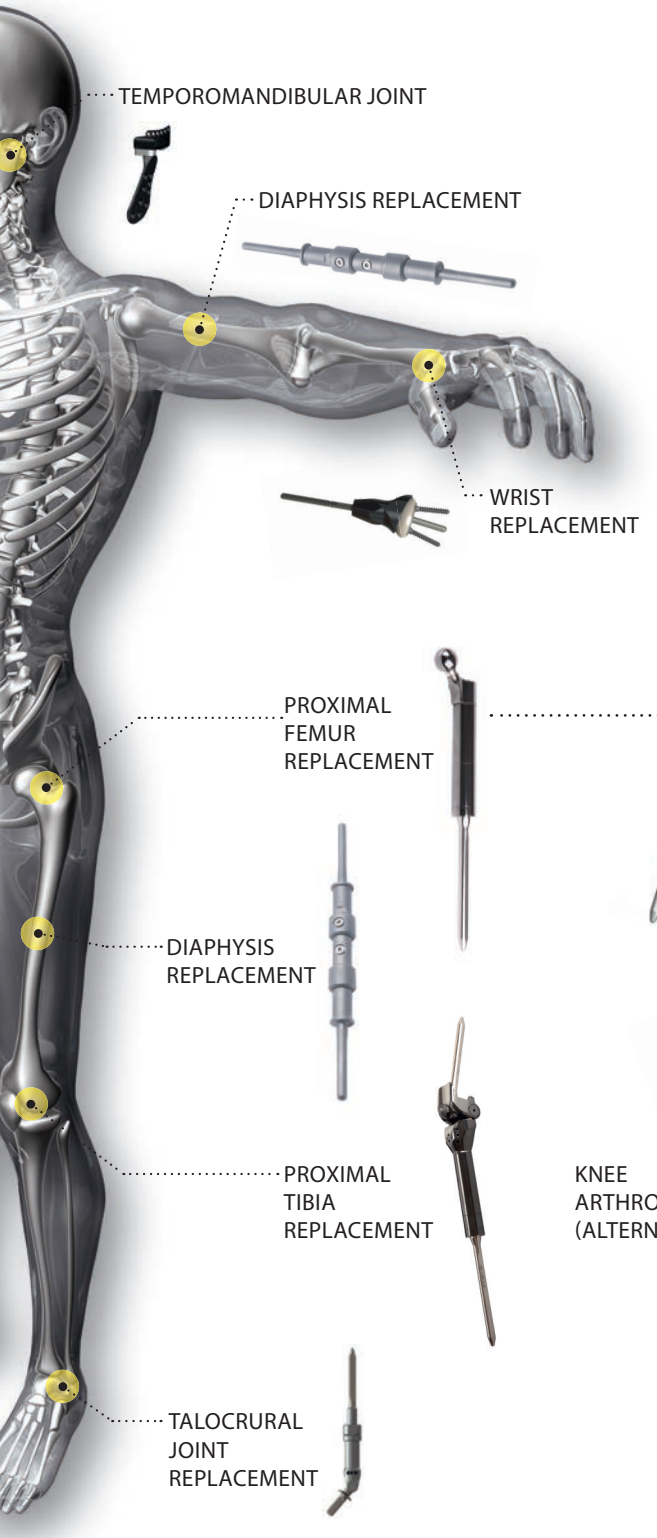
GROWING DISTAL FEMUR
REPLACEMENT

TOTAL TIBIA
REPLACEMENT

GROWING PROXIMAL TIBIA
REPLACEMENT



NON-INVASIVELY GROWING IMPLANTS ARE AT THE DEVELOPMENTAL STAGE.



TEMPOROMANDIBULAR JOINT

DIAPHYSIS REPLACEMENT

WRIST REPLACEMENT

MANDIBULAR REPLACEMENT

PELVIC PLATE FOR COTYLOID CAVITY

PROXIMAL FEMUR REPLACEMENT

GROWING PROXIMAL FEMUR REPLACEMENT

DIAPHYSIS REPLACEMENT

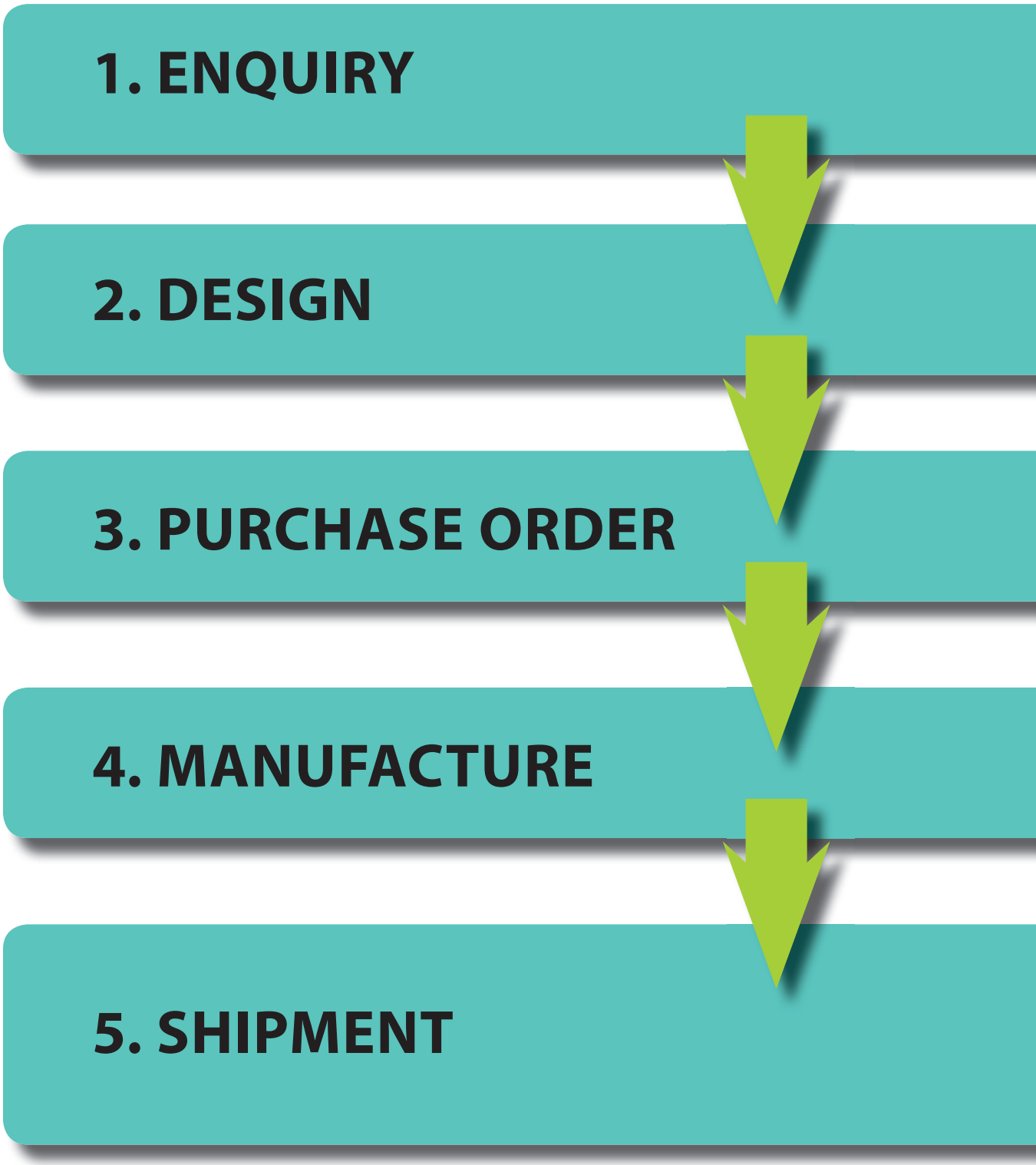
LARGE PELVIS REPLACEMENT WITH COTYLOID CAVITY

PROXIMAL TIBIA REPLACEMENT

KNEE ARTHRODESIS (ALTERNA)

TALOCRURAL JOINT REPLACEMENT

CUSTOM-MADE IMPLANT MANUFACTURING PROCESS



X-RAYS AND/OR DICOM DATA FROM CT/MRI, WITH ADEQUATE RESOLUTION FOR SETTING UP A COMPUTERIZED 3D MODEL (DISTANCE BETWEEN THE SECTIONS ≤1 MM)

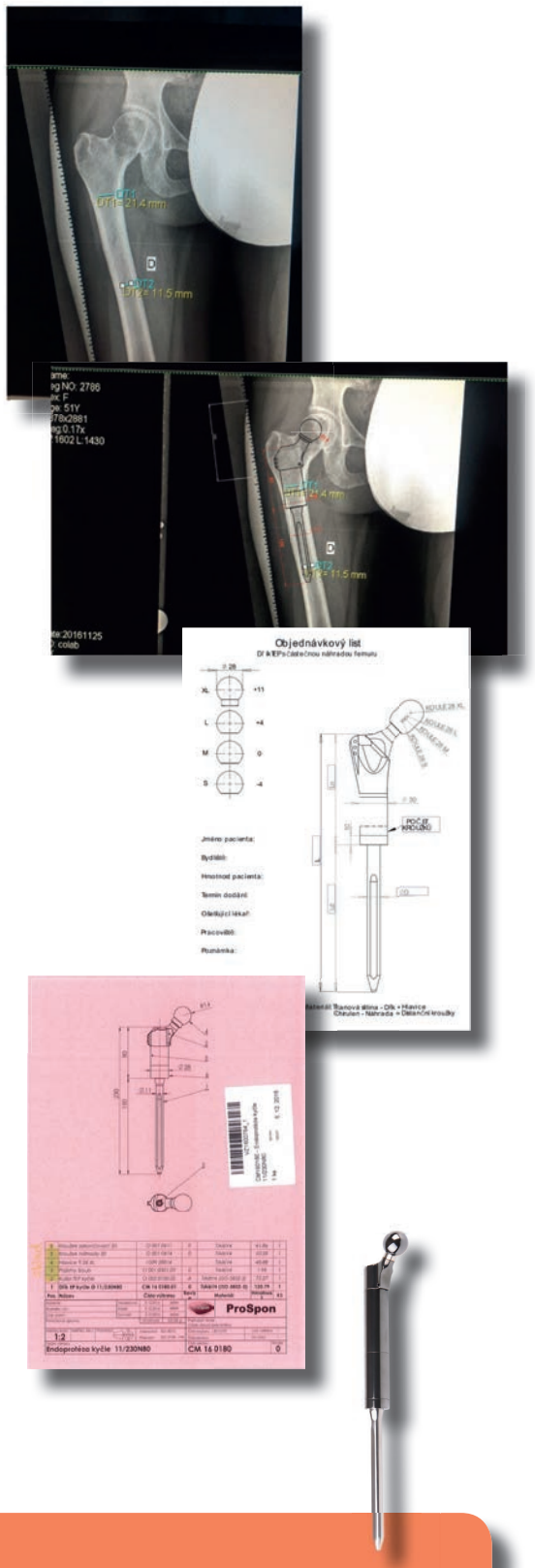
THE DESIGN DEVELOPMENT PHASE LENGTH DEPENDS ON FACTORS SUCH AS COMPLEXITY OF THE CASE, DOCTOR'S REQUIREMENTS, NUMBER AND LENGTH OF DISCUSSIONS, ETC. AND HENCE, CAN ONLY BE ROUGHLY ESTIMATED

ONCE THE DESIGN HAS BEEN APPROVED, THE DOCTOR CONFIRMS THE ORDER FOR THE SPECIFIC PATIENT, WITH ADEQUATE PRODUCT SPECIFICATION. PURCHASE ORDERS FOR SIMPLE IMPLANTS CAN BE DIRECTLY PLACED, PROVIDED THAT THE IMPLANT SPECIFICATION IS ADEQUATELY DETAILED

THE MANUFACTURING PHASE LENGTH DEPENDS ON THE COMPLEXITY AND HENCE, TECHNOLOGY REQUIREMENTS. ROUGH ESTIMATES ARE LISTED BELOW (SEE THE **TIME ESTIMATES** BOX)

THE PRODUCTS ARE DELIVERED EITHER NON-STERILE OR STERILIZED WITH ETHYLENE OXIDE, DEPENDING ON THE DOCTOR'S REQUIREMENT

WHEN DELIVERED, THE PRODUCTS ARE ACCOMPANIED BY A DECLARATION OF CONFORMITY, INSTRUCTIONS FOR USE AND THE CONFIRMED PURCHASE ORDER CONTAINING THE IMPLANT SPECIFICATION. ANY OTHER TECHNICAL DOCUMENTS ARE AVAILABLE ON REQUEST



TIME ESTIMATES:

1–3 DAYS FROM THE CONFIRMED PURCHASE ORDER FOR VERY SIMPLE IMPLANTS (HIP SHANK), DELIVERED NON-STERILE

UP TO 5 WEEKS FOR CUSTOM-MADE IMPLANTS, DELIVERED STERILE

NOTES

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MANUFACTURE & DEVELOPMENT

ProSpon, spol. s r.o.
Jiřího Voskovce 3206
272 01 Kladno
Česká republika

SALES CZECH REPUBLIC

tel: +420 312 247 763
expor@medin.cz
www.medin.eu

www.prospon.cz

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