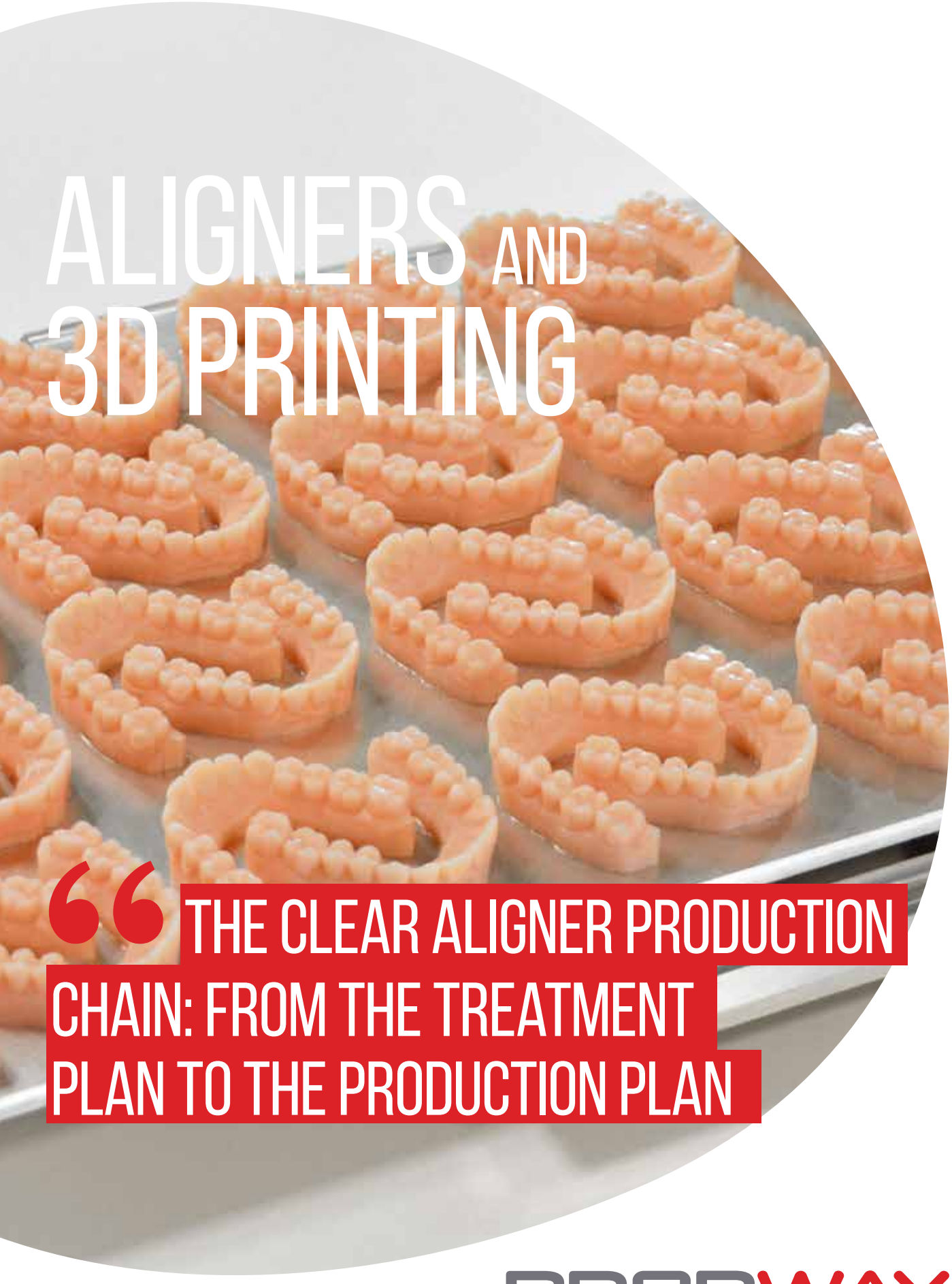
ALIGNERS AND 3D PRINTING



“THE CLEAR ALIGNER PRODUCTION CHAIN: FROM THE TREATMENT PLAN TO THE PRODUCTION PLAN

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THE PRODUCTION CHAIN

INTEROPERABILITY OF THE ENTIRE PRODUCTION CHAIN

In order to propose a high-performance, consistent and competitive working offer to its customers, **Prodways insists on perfect interoperability between its own devices and the other constituent components that together make up the dentition aligner production chain**. Each component is technically evaluated for optimal integration into the system, and key equipment is even selected from preferred partners to ensure complete continuity of the production flow. Typically, the production line consists of the following components:

THE INTRAORAL SCANNER, USED TO CREATE A PERFECT DIGITAL MODEL OF A PATIENT'S DENTITION, WHICH REPLACES A TRADITIONAL IMPRESSION FOLLOWED BY A SCAN TO MODEL IT DIGITALLY,

THE PROCESSING SOFTWARE WHICH, BASED ON THE DIGITAL MODEL PRODUCED BY THE SCANNER, SIMULATES AND THEN PLANS THE DIFFERENT PHASES AND STRAIGHTENING ACTIONS TO BE MADE TO A PATIENT'S DENTITION UNDER THE MEDICAL SUPERVISION OF THE SPECIALIST,

THE PRODUCTION PLANNING SOFTWARE TO CONTROL ADDITIVE MANUFACTURING

AN ADDITIVE MANUFACTURING PLATFORM OR 3D PRINTER WHICH, ON THE INSTRUCTIONS OF THE MANUFACTURING SOFTWARE, AUTOMATES THE IMPLEMENTATION OF THE VARIOUS TOOLS AND MANUFACTURING PHASES: POSITIONING OF THE TRAY RECEIVING THE IMPRESSIONS MADE, APPLICATION BY LAYER OF PHOTOSENSITIVE RESIN ON THE POLYMERIZATION AREAS DEFINED BY THE DLP IMAGERS,

A CLEANING AND POST-COOKING SYSTEM TO PREPARE IMPRESSIONS FOR THE THERMOFORMING PHASE,

THE PRODUCTION CHAIN

THE GUARANTEE OF OPTIMAL FUNCTIONING

THE THERMOFORMING MACHINE THAT APPLIES TRANSPARENT MATERIAL ON THE IMPRINTS TO PRODUCE DENTAL ALIGNERS

LASER MICRO-ENGRAVING IDENTIFICATION SYSTEM TO IDENTIFY THE ALIGNERS OF THE SERIES CORRESPONDING TO EACH PATIENT AND TO COMPLY WITH MDR AND FDA RECOMMENDATIONS FOR MEDICAL DEVICES,

THE CUTTING AND POLISHING SYSTEM,

A FINAL CLEANING SYSTEM TO ELIMINATE ANY POTENTIAL IMPERFECTIONS, AND ENSURE THE ASEPSIS OF THE ALIGNERS,

THE PACKAGING OF ALIGNERS ORDERED AND IDENTIFIED IN THE PATIENT BOX.

IN ORDER TO ENSURE PERFECT COORDINATION OF ALL THESE ELEMENTS, A PILOTING AND CONTROL SYSTEM OF THE CHAIN ENSURES THE METICULOUS FOLLOW-UP OF ALL THESE UNIQUE ELEMENTS.

The production chain is therefore made up of different hardware and software selected, advised and supplied (as far as the 3D printer and laser engraving system are concerned) by Prodways, which checks and validates their interoperability in order to guarantee optimal operation and flawless production for the laboratory.

THE SCANNER

3D MODEL CONSTRUCTION

Over the years, dental scanners have become a very common tool in many practices where it is a very useful complement to conventional radiography. Scanners are used to quickly capture a three-dimensional image, an easy process with minimum intrusion and no special preparation. The image capture is not only a comprehensive information tool that can be manipulated from all angles on the screen, it is also a digital model that is immediately transferable to the laboratory and serves to prepare procedures or help in the manufacture of prostheses.

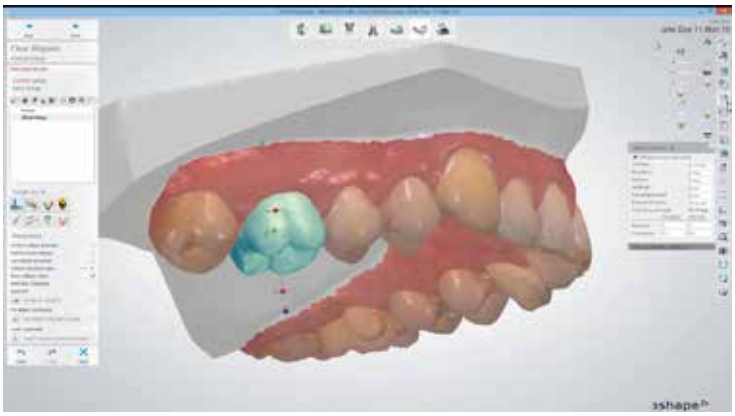
Once inserted in the mouth, the scanner is manipulated by the practitioner so that the patient's dentition can be "seen" from all possible angles by the transmitter/receiver. On-screen video feedback allows the operator to check that all the images needed to build the 3D model are taken and transmitted to the computer. The computer is equipped with graphic software that assembles the different 2D images to build the three-dimensional pattern, a true digital clone of actual dentition. Once finalized, this 3D model can be manipulated on the screen through all 3 axes and then magnified using an ordinary computer mouse. It is then potentially possible to visualize teeth more conveniently than when working directly on the patient to take measurements, use high-definition to zoom in on details and can obviously be archived. Above all in the manufacturing process of aligners, the 3D scan is immediately post-processed for interpretation by business software. The scan saves time by immediately bringing the orthodontic treatment into the digital workflow with direct transmission of the 3D model to the laboratory.

As an alternative to scanning, we can use the conventional impression by applying a tray filled with a special hardening filler. This procedure requires that the mold made in this way be scanned to produce the digital reference model; this will then be used by orthodontists to carry out their treatment plan.

For an aligner production chain, Prodways recommends in particular the use of scanners and 3Shape professional software programs that are perfectly optimized to work with its ProMaker MovingLight 3D printers.

“ PROFESSIONAL SOFTWARE

A TREATMENT PLAN WITH MICROMETRIC PRECISION



Once the three-dimensional model is completed, the orthodontic treatment plan is prepared and will subsequently be used to schedule the production of aligners. **Beforehand, the model can be used to visually explain to the patient in before/after mode what his or her teeth will look like at the end of the treatment.**

The 3D file generated by the scan is transmitted to the specialist, who is a dental professional but who may also be a specialized technician employed in a laboratory for the production of aligners. At this stage, we need to implement professional software that will potentially be used to merge the 3D file from the scanner with the digital X-rays taken from the patient’s teeth in order to enhance the reference model.

The technician will then develop the detailed treatment plan according to the medical recommendations that were previously transmitted. The software first separates the teeth from their gums, which are distinguished by their difference in density, thus enabling individual canines, molars and incisors to be “rotated” in order to virtually correct their implantation. The technician does not necessarily have to be a qualified orthodontist because he or she is assisted by professional software that applies rules and settings acting as a reference and “safeguard” with **final medical approval required before proceeding to the next step.**

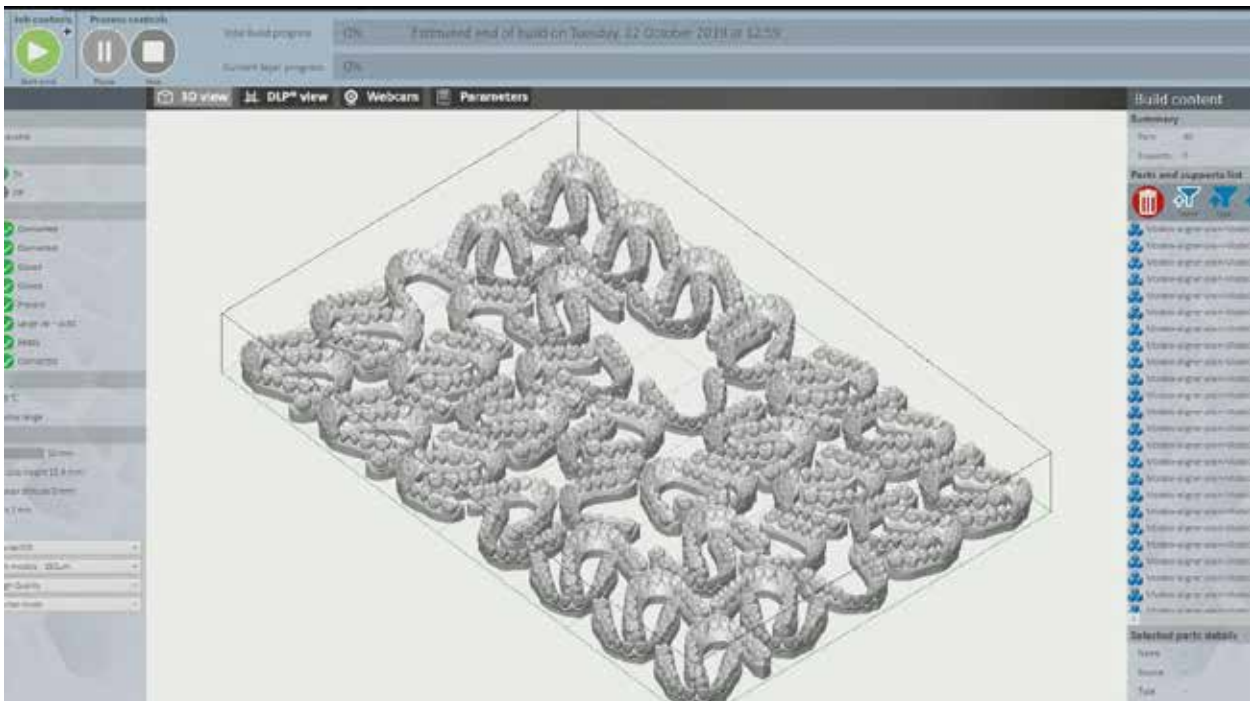
PROFESSIONAL SOFTWARE

A TREATMENT PLAN WITH MICROMETRIC PRECISION

The most advanced working methods are also beginning to integrate artificial intelligence, which, based on thousands of memorized cases and on this “deep learning”, defines rules of procedure for the manipulation of the digitized teeth displayed on the screen.

Between the initial state of teeth and the simulated final positioning, **the professional software will define several gradual stages - from less than 10 to 50 or more per jaw - which will require the production of as many aligners** as the patient will successively need to wear, on average 20 hours a day.

The aligners also have the advantage of being able to show the patient the final configuration of his teeth after treatment.



ADDITIVE MANUFACTURING

FROM THE TREATMENT PLAN TO THE PRODUCTION PLAN

Once formulated and potentially validated by a simulation process, the treatment plan has to be transformed into a production plan that will serve as a guide for the additive manufacturing machine or 3D printer. Prodways is the undeniable standard in this field of application thanks to its unique, highly reliable, ultra-high precision and very productive technological solution that we call MovingLight.

1

BUILD PLATE
UP TO
55 ALIGNERS

2

RESOLUTION
HIGH DEFINITION
1920 X 1080 PIXELS

3

40 μm NATIVE
XY RESOLUTION

4

PERFECT POLYMERIZATION
SURFACE

ADDITIVE MANUFACTURING

10 TO 50 ALIGNERS PER PATIENT REQUIRED

The principle of Prodways ProMaker machines is as follows:
The size of a refrigerator, this concentrate of technology consists of a mobile production platform that can simultaneously support up to 55 models for thermoforming and a mobile image projection system. Inspired by the principle of consumer DLP video protection and offering HD resolution (1920x1080 pixels), this device replaces RGB (red-green-blue) illumination with an ultra-violet light source (UV-A of wavelengths between 385 and 405 nm) that projects an image generated from the 3D model onto a photosensitive resin.

In contact with light, the resin hardens by polymerization and takes shape on the irradiated parts. The unique XY resolution of Prodways printers associated with layer thickness make it possible to obtain precision parts that meet high expectations from all dental applications. Each model, identified by a unique identification generated by the 3D modeling software, is built in positive, successive phases until it constitutes a replica of the half dentition at one stage of its treatment.

To optimize its additive manufacturing process, Prodways formulates and produces its own resins so that they are perfectly suited to the method of application by layers and UV polymerization. This is the only consumable that needs to be supplied at this stage of production.

ADDITIVE MANUFACTURING

ABOUT FIFTY PREFORMS IN LESS THAN AN HOUR

To optimize the additive manufacturing process, Prodways formulates and produces our own resins to be perfectly suited to each application by layer and polymerization under light. This is the only consumable that is needed at this stage of production. The mobility of the imager, resin dispenser and construction plate make the ProMaker machines from Prodways fully automated tools, ensuring high productivity as they can create about fifty preforms in less than one hour. In addition, Prodways 3D printing guarantees the repeatability of the entire process with extreme precision and flawless quality, regardless of the technician's specific expertise or dexterity.
The principle of the mobile HD imager also allows Prodways to be the only industrial player to offer a resolution of 42µm over such a large manufacturing area.

- ✓ FULLY AUTOMATED TOOLS
- ✓ HIGH PRODUCTIVITY GUARANTEED
- ✓ REPEATABILITY WITH HIGH PRECISION
- ✓ HIGH QUALITY RESULTS

Guaranteeing this very high resolution without compromising the productivity of the machine is a determining factor and gives the practitioner and the operator the assurance that the patient will not feel any discomfort since the aligners will be adjusted to the shape of his or her teeth with micrometric precision.

Mass production in limited times is in fact essential to meet the requirements of this market, as the delivery times requested are generally rather short and the treatment of each patient may require the manufacture of up to several dozen models of aligner. As a result, the use of high-productivity 3D printers is a necessity to maintain good levels of profitability and customer satisfaction.

PREPARATION FOR THERMOFORMING

SEPARATION OF FORMS, CLEANING AND CONFORMITY CHECK

Once the additive manufacturing sequence has been completed, we need to prepare the 3D printed shapes for the next production phase, namely the aligners themselves. For this purpose, the production plate is extracted from the Prodways machine in order to proceed with finishing the shapes. This starts with the separation of elements from each other.

At this stage, it is also possible to verify the conformity of impressions by checking them with a scanner, a procedure that generates a point cloud data to facilitate comparison with the original 3D digital model. This control is usually carried out on a sample chosen from a series at random. To ensure that the future clear aligners are a perfect fit for the teeth that need to be straightened.

Individual cleaning with an alcohol-based product or in a centrifuge is carried out prior to thermoforming.

THERMOFORMING

FILM APPLICATION ON THE PRODUCTION TRAY

Once the shapes have been prepared, they are placed on a production tray, which is introduced into a thermoforming machine consisting of a heating surface, a film holder and a vacuum pump. The principle is to apply the thick, transparent, heat-softened film firmly to the items grouped together on the production tray, taking advantage of the air vacuum created by the pump. The suction phenomenon enables the film to fit tightly onto the entire impression, teeth and gums, down to the smallest details to perfectly embed the aligner on the patient's half-jaw. **The thermoforming machines are designed to use films of different thicknesses, chosen according to the patient's needs** and which will result in precise heating and cooling times and guarantee perfect molding followed by adequate hardening. Operation of the machine is made possible by constant digital control and does not require high-level technical skills. Large thermoforming machines can produce up to ten alignment trays in a single operation.

To ensure a consistent production line for aligners, Prodways recommends Dreve's thermoforming machines in particular, but the choice remains totally open and ultimately depends on the preferences of each manufacturer.

MARKING, CUTTING AND FINISHING

TRACEABILITY OF ALIGNERS IS IMPERATIVE

Once thermoforming is complete, the molded plate, clearly identified to be associated with a patient record, is removed from the machine for finishing work.

The aligners must be marked beforehand as they are intended for a patient who will have to wear between 10 and 50 of them throughout his or her treatment. It is therefore necessary to precisely identify the name and the rank defined by the order of treatment without this information appearing too visibly when the person smiles or opens their mouth. The markings comply with the increasing MDR and FDA expectations in relation to U.D.I. (Unique Device Identifier) specific to medical products.

This marking requirement presupposes extremely precise traceability of the trays throughout the production cycle and a discreet, indelible and invisible method of inscription. Several techniques are available, the most efficient of which is laser marking.

This can be done by means of special equipment integrated into the production line, at the end of the process, or in a finishing machine using various tools and operating automatically. Prodways also offers its own marking station that fits perfectly into the production flow and allows the choice of fonts for both the recognition of identifiers and the marking itself.

The 3D impressions covered by the aligners are then separated from each other. Then, piece by piece, the excess film is cut around each piece to free each gutter from the shape serving as a positive mold. This cutting can be done with a sharp tool, a small milling machine or an automated multifunction system.

Similarly, the final polishing can be done on the disc with a precision portable electric tool or in a dedicated or multifunction machine. The choice of tool depends directly on the size of the manufacturing unit, its objectives in terms of production volume and the level of investment made to equip it. However, finishing work carried out by hand can be justified if the laboratory wants to offer a high level of service and quality for the final product, as well as a certain degree of customization, which involves having operators with great dexterity, a common qualification among prosthetists.

PACKAGING AND DELIVERY

ALIGNERS ARE PACKED BY THE DURATION OF USE FOR EACH PHASE

Once the aligners are marked, carefully deburred, polished, and cleaned again they are ready for use. At this stage some laboratories find it necessary to do a control scan again to make sure that the aligners processed are those intended for a clearly identified user.

But first, they must be packaged in protective packaging **that clearly facilitates the identification of each tray in the exact order of use in relation to the treatment plan and schedule.** This document must not only list the items by their identifier but also indicate the length of each phase, i.e. the period during which each aligner must be worn. The treatment period usually lasts from several months up to two years. For complex cases, patients are often assisted by their healthcare practitioner.

At this stage, practitioners have a major educational role since **they must make the patient aware that any inconsistency in the wearing of the aligners can undermine the treatment and render it inoperative.** In countries where the role of the practitioner is not considered as critical, the presentation of the treatment, in its informative packaging accompanied by its application schedule, is essential and must in itself encourage the patient to continue his or her treatment.

ORGANIZATIONAL MODELS

COMPLEMENTARY PARTNERSHIPS

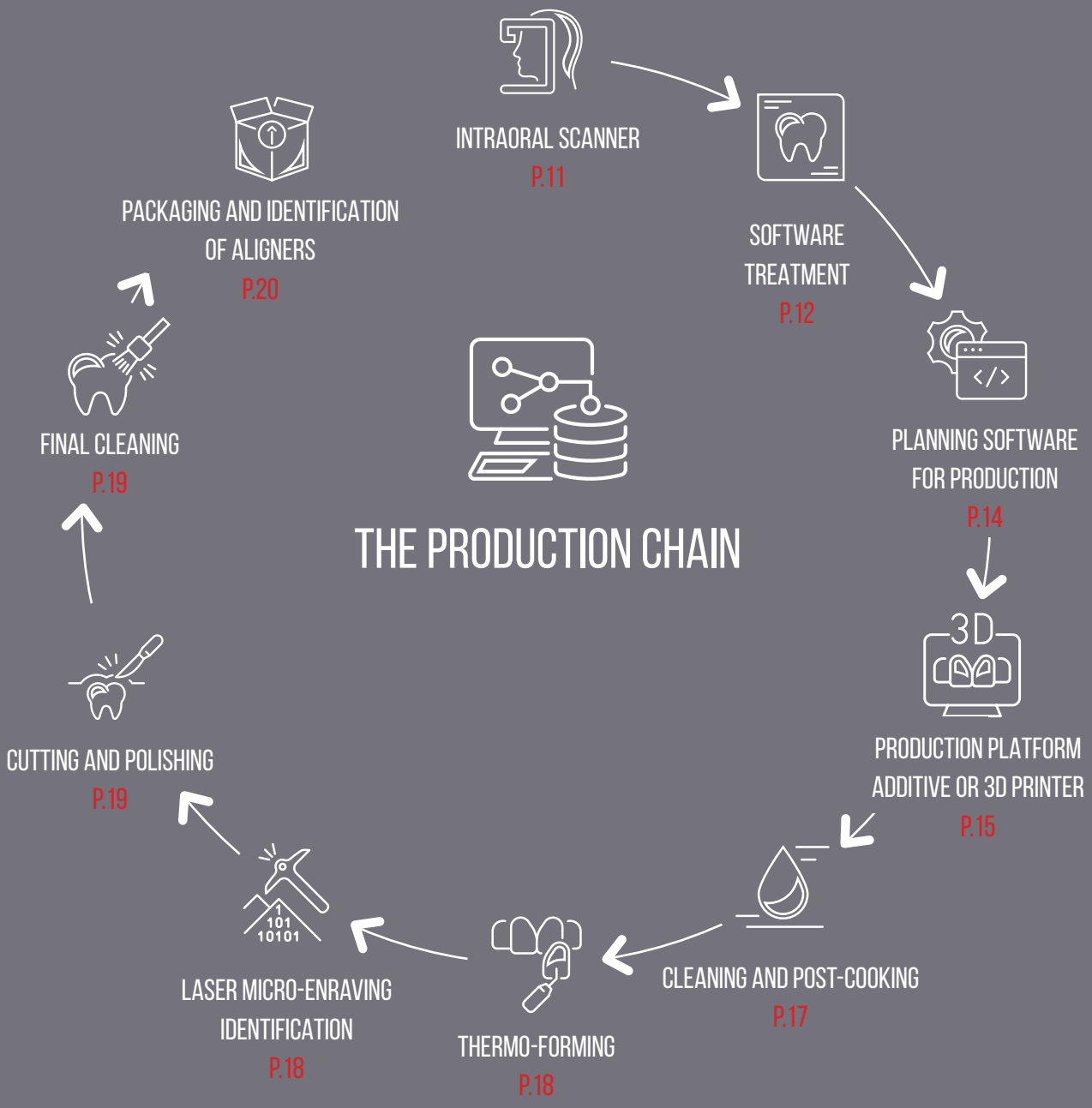
Depending on the situation, economic models, and national regulations, several production types are possible.

Practitioners, alone or more certainly in group practices, may equip themselves with all of the necessary equipment and have assistant technicians perform all of the operations. More often, the impression or scan of the teeth is taken in the dental practice, while the other production phases (additive manufacturing, thermoforming, finishing and packaging) are outsourced to one or more service providers. Finally, in regions where the technique of aligners could be self-prescribed for esthetic reasons, and of a purely commercial nature therefore outside of dental care, the impression is sometimes taken by patients themselves according to an operating mode included in the kit that they receive at home and send back to the provider. In this situation, most of the technical resources of the manufacturing chain are included, sometimes in highly automated units, and deliver a ready-to-use product along with its treatment plan, which is the sole responsibility of the patient.

To respond to all identified scenarios, manufacturers offer machines of all sizes adapted to all modes of production, from custom manufacturing for the needs of well-identified patients, to small-scale artisanal production in small series, to industrial units capable of delivering thousands of aligners per day. Prodways' range of 3D printers can thus meet all production configurations with excellent returns on investment.

However, the configuration and size of a production line, whether established in one place or spread out between several operators, is no guarantee of a consistent process capable of delivering dental orthotics that perfectly meet the patient's needs. To achieve this consistency, the production flow must be composed of steps that are perfectly connected to each other in a unified ecosystem combining digital information, machines and materials that "interoperate" perfectly. For this reason, Prodways has partnered with industrial operators in technical segments complementary to its own to ensure its customers that the production chain proposed to them is fully consistent.

THE PRODUCTION CHAIN



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