The USABILITY ENGINEERING team carefully reviews proposed design changes resulting from engineering and manufacturing constraints to determine their potential impact on USABILITY or SAFETY. When significant USABILITY ENGINEERING concerns arise, the relevant decision-makers should have a candid discussion of issues and tradeoffs before any design changes are implemented.

It is increasingly common to augment traditional, written specifications with physical simulations of the USER INTERFACE such as appearance models and/or computer-based models. A microprocessor-controlled MEDICAL DEVICE is particularly amenable to the use of functional prototypes. In this case, an interactive implementation of the MEDICAL DEVICE can include both a computer-based simulation of a screen-based USER INTERFACE as well as physical attributes of the proposed MEDICAL DEVICE (e.g. a syringe infusion mechanism for an infusion pump). It is useful to employ software tools that facilitate rapid prototyping to allow changes at low cost.

D.4.6.2 Hardware USER INTERFACE

When designing a hardware USER INTERFACE, specifications might include:

– a control panel layout drawing that shows the appearance and arrangement of MEDICAL DEVICE displays and controls. Such drawings are usually augmented by a written rationale that covers topics such as functional grouping, protection against accidental actuation of controls, and viewing angle considerations;

– an anthropometric analysis diagram (a graphical analysis of the physical relationship between the MEDICAL DEVICE and individuals of varying size that establishes the design's physical suitability for the intended USER population);

– a description of expected USER interaction with the displays and controls (e.g. how controls and displays change as a result of MEDICAL DEVICE internal events and USER actions).

D.4.6.3 Software USER INTERFACE

When designing a software USER INTERFACE, specifications might include:

– all screen and window layouts including labeling, fonts, use of color, and graphics;

– the appearance and behavior of all on-screen controls;

– all dialog flow, including audible events;

– all hard copy report designs;

– a description of expected USER interaction with the displays and controls (e.g. how controls and displays change as a result of MEDICAL DEVICE internal events and USER actions).

D.4.6.4 Other useful USABILITY ENGINEERING tools

When specifying a USER INTERFACE design, it can also be useful to produce:

– a conceptual model diagram that illustrates the USER INTERFACE high-level structure (see Figure D.2);

– a USER INTERFACE map – an illustration (typically a flowchart) showing the relationships among various screens;

– a screen template – a generic layout for the computer screens;

– a story board – a set of software screen printouts that can be cross-indexed to templates and written specifications;

– a style guide – a set of written rules that ensure consistency by governing the graphical composition of screens and means of interaction.

D.4.7 Design evaluation

D.4.7.1 General guidance

The products of each design activity are assessed throughout the development cycle. These activities are iterative and cumulative, and should be applied to all USER INTERFACES (software, hardware, documentation, etc.) for all types of USERS (maintainers, installers, etc.). The result is a working model that is subjected to final VALIDATION testing. The difference between VERIFICATION and VALIDATION is that VERIFICATION insures that the design meets design requirements, while VALIDATION insures that the final production model addresses the intended USER needs.

A comprehensive design evaluation is required to be completed before finalizing the design. Typically, there are pressures to freeze a design prior to detailed engineering and software coding. Once the design is frozen, significant design changes are disruptive, time-consuming, and costly. For example, unless a serious HAZARDOUS SITUATION was uncovered, a MANUFACTURER would have difficulty justifying the cost of a major change to a control panel, such as rearranging or adding pushbuttons, after ordering expensive tooling. More likely, the specified design would remain frozen, and other options would be considered to address USABILITY concerns such as special labeling, comments in the USER documentation, or additional training. However, these types of fixes are often ineffective and are always less desirable than getting the design right the first time.

D.4.7.2 Design VERIFICATION

The work products and other descriptive materials that characterize the design should be tested against criteria derived from the design requirements. These products, which can include drawings, task descriptions, mock-ups, and dynamic computer representations, serve as tools in task, storyboard, and heuristic analyses, mock-up reviews, and USABILITY tests. Identified potential errors and/or MEDICAL DEVICE failures are integrated into RISK ANALYSES.

Without repetitive evaluation during development, the trial-and-error aspects of development are not sorted out until product VALIDATION (discussed in D.4.7.3). Insufficient attention to VERIFICATION activities can become apparent during tests of production models in the form of unsafe, inefficient MEDICAL DEVICE installation and operation (i.e. critical errors, performance bottlenecks, and slow task performance). The cost of correcting problems identified during VERIFICATION is much less than the cost of retrofitting production models.

Seemingly, minor design changes can have a significant effect on ultimate MEDICAL DEVICE performance. Any significant design changes should be incorporated into revised RISK ANALYSIS to assure that such changes have not introduced any additional HAZARDS or HAZARDOUS SITUATIONS.

The results of these evaluations often lead to design requirement refinements and facilitate informed design decisions involving issues such as:

– the allocation of functions to USERS, software, and hardware;
– the logic, flow, and intuitiveness of task steps given the hardware/software USER INTERFACE;
– any design characteristics that could allow or induce errors;
– potential HAZARDOUS SITUATIONS and alternative design solutions;
– tasks that are overly time-consuming;
– markings or displayed information that are difficult to comprehend or are subject to misinterpretation;
– safeguards against REASONABLY FORESEEABLE MISUSE.

D.4.7.3 Production unit final VALIDATION

Evaluation of production units employ methods to assure that the MEDICAL DEVICE meets USER needs and INTENDED USE (i.e. design VALIDATION). Testing can be conducted under actual or simulated conditions. The resulting data (e.g. task time, errors, observed bottlenecks) should pertain directly to safe, efficient performance. Normally, the MEDICAL DEVICE is evaluated before actual use on PATIENTS, although additional data can be gathered during clinical trials. Later, post-market studies with a marketed MEDICAL DEVICE can provide useful feedback about design strengths and weaknesses.

During VALIDATION, all functions are being scrutinized, rather than individual functions and their related USER INTERFACE features. Given a thorough VERIFICATION effort, the USER INTERFACE design is likely to be substantiated during final VALIDATION. However, subtleties in operation that were not apparent during VERIFICATION can emerge in final testing. Given a design based on a structured USABILITY ENGINEERING approach, problems uncovered during VALIDATION are usually relatively minor and the required design changes modest.

D.5 Methods and techniques used in the USABILITY ENGINEERING PROCESS

D.5.1 General

Many techniques, tools, and methodologies have been developed to help USABILITY ENGINEERING practitioners design a safer and more usable MEDICAL DEVICE. No single method is best in all situations, and several different ones are typically used during product design. Decisions about which methods should be used at what stages in the design cycle are based upon the USABILITY ENGINEERING issues of the design and can best be made by USABILITY ENGINEERING professionals. Methods that generate objective, auditable data are preferred. However, both objective and subjective data are important to a comprehensive understanding of a design's successful and less successful attributes. Regardless of the methods, the results are only credible when research participants are representative of the people who will perform the task(s) under evaluation. The following section briefly describes major USABILITY ENGINEERING techniques and methods. For more information, please see references in the bibliography. These approaches can be used in addition to obtaining relevant data from the technical literature and applying it intelligently to a given problem. The techniques are listed alphabetically.

D.5.2 Cognitive walk-through

Cognitive walk-throughs involve a structured review of USER requirements for the performance of a sequence of predefined tasks. A cognitive walk-through early in the design PROCESS permits evaluation of different preliminary design concepts. Later in the design PROCESS, when designs have become better defined, a cognitive walk-through can still be productive [29].

D.5.3 Contextual inquiry and observation

Contextual inquiry generally involves unobtrusive observation of USERS performing relevant tasks associated with the MEDICAL DEVICE or similar MEDICAL DEVICES in the actual use environment [14], [23]. Observing and working with USERS in their normal environment, permits a better understanding of the relevant tasks and workflow. This method is typically used early in the design PROCESS (during problem identification, requirements analysis, and MEDICAL DEVICE conceptualization) to understand USERS and their tasks. This technique generally does not reveal cognitive PROCESSES, attitudes, or opinions.

D.5.4 Design audits

In a design audit, the proposed USER INTERFACE attributes and components are compared against a checklist of good design practices. The checklist itemizes characteristics that the USER INTERFACE should possess, along with some method of recording whether or not the interface meets the listed standards. Design audits are relatively quick and cost-effective but can yield only a superficial understanding of USER INTERFACE issues.

D.5.5 MEDICAL DEVICE comparisons and functional analysis

Alternative MEDICAL DEVICES or alternative MEDICAL DEVICE concepts can be compared by arranging a list of MEDICAL DEVICES and their attributes in a matrix format. Attributes of each of the alternatives are assigned ratings or scored on a series of criteria. Such comparisons can be useful for understanding which design approach best meets USER needs. For example, one might develop a matrix of several comparable MEDICAL DEVICES' physical attributes (e.g. weight, dimensions, texture, etc.) to facilitate cross-MEDICAL DEVICE comparisons.

D.5.6 Expert reviews

Expert reviews depend on the knowledge and experience of USABILITY ENGINEERING specialists to ascertain design strengths and weaknesses and to recommend opportunities for improvement. An expert review can be performed on design-concept sketches as well as on working prototypes. Many serious design flaws can be detected early and without incurring USER testing costs. However, if used in isolation, this technique is unlikely to detect all of the design flaws.

D.5.7 Functional analysis

A functional analysis provides a representation of the functions and events required to meet system objectives. For example, important functions for brachytherapy are clinical evaluation of the PATIENT, PATIENT preparation, treatment planning, treatment delivery, post-treatment MEDICAL DEVICE removal, communication, recordkeeping, quality assurance, and maintenance [15]. This type of analysis is used to determine the appropriate allocation of functions to humans versus machines. There are numerous types of functional analyses, including operational sequence diagrams and Functional Analysis Systems Technique (FAST) as well as computer simulation and modelling techniques such as Systems Analysis of Integrated Network of Tasks (SAINT) [26], [34].

D.5.8 Heuristic analysis

Heuristic analysis is the evaluation by clinical or USABILITY ENGINEERING experts of a MEDICAL DEVICE or system through the assessment of how it conforms to well-established human-machine interface design rules [29]. It is particularly useful early in the design PROCESS for discovering problematic aspects of the USER INTERFACE. In addition, it is useful for comparing potential USER INTERFACE designs because the assessments for each rule can be compared across products. This method is usually quick and inexpensive. The value of heuristic analysis is limited if, as generally happens, it is not applied in the actual use environment, and typical USERS are usually not involved in the evaluation. Heuristic analysis often yields excellent design insights early in the development PROCESS. Heuristic analysis should be used in conjunction with other techniques that acquire input from USERS, especially when used later in the design PROCESS.

D.5.9 Interviews

Often it is useful to discuss design issues with a small group of USERS, especially when the goal is to generate ideas or reach consensus. Interviews can also be conducted individually. This method is for information gathering, not for evaluation. Structured (or directed) interviews are

useful in circumstances in which the goal is to uncover answers to specific questions, often when designers are fairly well along in the design PROCESS. Unstructured interviews, on the other hand, are useful for gaining initial insights about designs under conditions in which the designer wants to avoid biasing the interviewee in any particular direction [17], [35].

D.5.10 Participatory design

Participatory design involves providing potential USERS with tools that allow them to "become design team members". Examples of the many tools available ([33]) include 3D models of components that USERS might be asked to arrange in a preferred configuration or 2D representations that USERS arrange to represent their ideas about a product's design. Similarly, USERS could be asked to direct the efforts of an illustrator to represent their ideas or to manipulate options on a computer screen.

D.5.11 Prototyping

Prototyping involves creating a MEDICAL DEVICE model that can be used in various evaluation activities. Models can vary from "looks-like, works-like" prototypes with a high degree of fidelity to the final product, to low-fidelity rough simulations that only demonstrate a subset of MEDICAL DEVICE attributes. Examples of simulation and prototyping methods include screen simulation, software prototyping tools, physical models that are tethered to a computer, and physical models with embedded microprocessors [19], [36].

D.5.12 Questionnaires and surveys

Human-machine interface-related information and opinions are commonly collected via the telephone, the Internet, or written forms [28]. One benefit of this technique is that data can be easily and cost effectively collected from many USERS. This technique can be used early in design for broad USER studies, during other testing to obtain subjective information, and later to collect evaluations of a fielded product.

D.5.13 Simulated clinical environments and field-testing

Simulated clinical environments permit evaluation in a controlled manner in a setting containing some or all of the essential attributes of the actual clinical environment for which the MEDICAL DEVICE is being designed. Simulations facilitate creation of worst-case USE SCENARIOS and complex failures. A high-RISK MEDICAL DEVICE or one involving tasks that are more complex can be tested in high-fidelity simulators, such as a full-scale, simulated operating room with functional manikin. High-fidelity simulation allows the test team to evaluate dynamic interactions among multiple MEDICAL DEVICES, personnel, and task constraints.

Every MEDICAL DEVICE is ultimately "field tested" when it is marketed. However, USABILITY issues raised at this time can adversely affect commercial success. Field-testing of prototypes or pre-production models in the actual environment, although less controlled, is usually informative. Although field-testing can be most valuable for a complex MEDICAL DEVICE that demands extensive interactions with multiple USERS and other system elements. Even field-testing of a relatively simple MEDICAL DEVICE can reveal unanticipated interactions, USABILITY issues, and USE ERRORS [19], [36].

D.5.14 Task analysis

D.5.14.1 General task analysis

Task analysis is a family of systematic methods that produce detailed descriptions of the sequential and simultaneous manual and intellectual activities of personnel operating,

maintaining, or controlling a MEDICAL DEVICE or system. Task analysis can yield information about the knowledge, skills, abilities, and HAZARDOUS SITUATIONS associated with the completion of relevant tasks. Task analysis can be employed as early as design conceptualization to facilitate understanding and subsequent reengineering of an entire PROCESS. Later in the design cycle, task analysis can be used to evaluate a MEDICAL DEVICE prototype in actual or simulated use environments. The limitations of task analysis are that it can be time-consuming, and the large amounts of data that can be generated are sometimes difficult to analyze and interpret [20], [22].

D.5.14.2 Time-and-motion studies

One of the earliest USABILITY ENGINEERING techniques, time-and-motion studies, document people's discrete actions over time. The technique can be used to discover interferences and opportunities for streamlining, to determine if actions can be completed within established time constraints, or to examine the effect of a MEDICAL DEVICE'S use on PROCESSES and procedures [24], [27], [28].

D.5.14.3 Cognitive task analysis

Cognitive task analysis focuses on USERS' cognitive PROCESSES such as their mental model of the MEDICAL DEVICE or system operation [16], [25]. This technique provides a formal evaluation of the cognitive demands placed on USERS as they perform the tasks that the MEDICAL DEVICE replaces, supplements, or requires. Cognitive task analysis can also be used to evaluate how the MEDICAL DEVICE implementation changes how USERS think about the PROCESSES involved. In a related technique, cognitive modelling, task performance is predicted based on an analysis of the basic task requirements, the capabilities of the person performing the task, the available methods to perform the task, and the PROCESS by which a USER would select one of the available methods.

D.5.15 USABILITY testing

In USABILITY tests, actual USERS interact with one or more MEDICAL DEVICE models, prototypes, or production units to assess ease of learning, ease of use, EFFICIENCY, ease of remembering, and/or USER appeal [29]. USABILITY tests can be performed in a laboratory setting, in a simulated environment, or in the actual environment of INTENDED USE. USABILITY testing, especially when conducted in the field, can detect USE ERRORS. However, because the subject populations are small, low probability errors cannot be detected. For this reason, the use of additional techniques such as RISK ANALYSIS is essential.

D.5.16 USE ERROR analysis

USER INTERFACE designs should be evaluated throughout MEDICAL DEVICE development to determine the likelihood of specific USE ERRORS that could lead to HARM. Analysis can include review of relevant vigilance reports, incident reports, adverse event reports, customer complaints, MedWatch data, closed claim data, post-market surveillance data (e.g. CAPA – corrective action and preventive action; ISO 9001:2000, Subclauses 8.5.2 and 8.5.3) [6], precursor analysis, or use of critical incident analysis techniques. Several empirical and computer-based techniques exist for error modelling and analysis. Both Rouse [31] and Reason [30] discuss USE ERROR analysis in more detail.

D.5.17 Workload assessment

USER performance can be impaired by excessively high or low workloads. MEDICAL DEVICE use can affect workload and workload can impact how USERS interact with the MEDICAL DEVICE [27], [37]. Workload assessment helps to evaluate or predict the worker's cognitive capacity for additional tasks. Workload can be measured using psychological (e.g. subjective assessments,

perhaps obtained with questionnaires), procedural (e.g. effects on standardized performance metrics), or physiological (e.g. changes in heart rate) techniques. Workload assessment methods generally need to be VALIDATED and can be technically complex and difficult to analyze.

Annex E
(informative)

Questions that can be used to identify MEDICAL DEVICE characteristics associated with USABILITY that could impact on SAFETY

E.1 General

Subclause 5.1 requires that the MANUFACTURER identify characteristics related to the use of the MEDICAL DEVICE. Consideration of these characteristics is an essential step in identifying the HAZARDS and HAZARDOUS SITUATIONS as required in 5.3. One way of doing this is to ask a series of questions concerning the manufacture, use, and ultimate disposal of the MEDICAL DEVICE. If one asks these questions from the point of view of all the individuals involved (e.g. RESPONSIBLE ORGANIZATIONS, maintainers, PATIENTS, etc.), a more complete picture can emerge of where the potential HAZARDOUS SITUATIONS can be found. The following questions can aid the reader in identifying all the USABILITY characteristics of the MEDICAL DEVICE that could affect SAFETY.

The list is not exhaustive, or representative of all MEDICAL DEVICES, and the reader is cautioned to add questions that can have applicability to a particular MEDICAL DEVICE and to skip questions that are not relevant to the particular MEDICAL DEVICE. The reader is also cautioned to not only consider each question on its own but also in relation to each other.

E.2 Questions

E.2.1 Is the MEDICAL DEVICE supplied sterile or intended to be sterilized by the USER, or are other microbiological controls applicable?

Factors that should be considered include whether the MEDICAL DEVICE is intended for single-use or to be re-usable, and also any packaging, the shelf-life, and any limitation on the number of re-use cycles or type of sterilization PROCESS to be used.

Is the MEDICAL DEVICE properly marked to inform the USER whether it is for single use or to be re-used? Does the packaging clearly indicate any limitation of handling or shelf-life? The ACCOMPANYING DOCUMENT has to clearly indicate proper methods of and agents to be used for cleaning or sterilization, inform about frequencies of cleaning.

Of special interest from the perspective of USABILITY is the simplicity of disassembling/ reassembling and any USE ERRORS connected to these.

E.2.2 Are measurements taken?

Factors that should be considered include the variables measured and the accuracy and the precision of the measurement results. Also USERS have to be aware of frequencies at which measurements have to be initiated, parameters influencing the result, consumables needed, how to handle or interpret the results. Standard issues are legibility and exactness of displays. Neglecting routine maintenance also might cause wrong results.

E.2.3 Is the MEDICAL DEVICE intended for use in conjunction with medicines or other medical technologies?

Factors that should be considered include identifying any medicines or other medical technologies that can be involved and the potential problems associated with such interactions, as well as PATIENT compliance with the therapy.

E.2.4 Are there unwanted outputs of energy or substances?

Energy-related factors that should be considered include noise and vibration, heat, radiation (including ionizing, non-ionizing, and ultraviolet/visible/infrared radiation), contact temperatures, leakage currents, and electric and/or magnetic fields, as well as the adverse effects of noise, vibration, heat and waste products (exhaust gases) on physiology and psychology of USERS and thirds.

E.2.5 Is the MEDICAL DEVICE susceptible to environmental influences?

Factors that should be considered include the operational, transport, and storage environments. Factors include the transit environment extremes – shock, vibration, pressure, temperature and humidity as well as light, spillage, susceptibility to variations in power and cooling, magnetic and electromagnetic influences.

The ACCOMPANYING DOCUMENT has to clearly inform about limitations to the environment in which the MEDICAL DEVICE can be used. Ergonomics of the MEDICAL DEVICE (weight, design of handles, sharp edges) should be considered very carefully.

E.2.6 Are there essential consumables or accessories associated with the MEDICAL DEVICE?

Factors that should be considered include specifications for such consumables or accessories and any restrictions placed upon RESPONSIBLE ORGANIZATIONS or USERS in their selection of these.

The USER has to be aware of the use of the correct consumable, the remaining amount of them, whether accessories might be used with the MEDICAL DEVICE, how to assemble them and how to check their correct functioning.

E.2.7 Is maintenance and/or calibration necessary?

Factors that should be considered include whether maintenance and/or calibration are to be carried out by the USER or RESPONSIBLE ORGANIZATION or by a specialist. Are special substances or equipment necessary for proper maintenance and/or calibration?

E.2.8 Does the MEDICAL DEVICE have a restricted shelf-life?

Factors that should be considered include labeling or indicators and the disposal of the MEDICAL DEVICE.

E.2.9 Are there any delayed and/or long-term use effects?

Factors that should be considered include ergonomic and cumulative effects. Long time exposure to vibration, noise, heat, gases as well as poor ergonomics (wear on joints, muscles and nerves etc.) need to be considered.

E.2.10 To what mechanical forces will the MEDICAL DEVICE be subjected?

Factors that should be considered include whether the forces to which the MEDICAL DEVICE will be subjected are under the control of the RESPONSIBLE ORGANIZATION, USER, or controlled by interaction with other persons. Examples include: sudden release of locks (bed headrest), the control of mechanical motion by persons distant from the moving equipment (remote control of operating tables) as well as well placed handles on mobile equipment.

E.2.11 Is the MEDICAL DEVICE intended for single use?

Factors that should be considered include, does the MEDICAL DEVICE self-destruct after use? Is it obvious that the MEDICAL DEVICE has been used?

E.2.12 Does installation or use of the MEDICAL DEVICE require special training or special skills?

Factors that should be considered include the novelty of the MEDICAL DEVICE and the likely skill and training of the person installing the MEDICAL DEVICE.

E.2.13 How will information for safe use be provided?

Factors that should be considered include:

– whether information will be provided directly to the USER by the MANUFACTURER or will it involve the participation of third parties such as installers, care providers, health care professionals, or pharmacists and whether this will have implications for training; and

– commissioning and handing over to the USER and whether it is likely/possible that installation can be carried out by people without the necessary skills.

E.2.14 Can the USER INTERFACE design features contribute to USE ERROR?

Factors that should be considered are USER INTERFACE design features that can contribute to USE ERROR. Examples of interface design features include: control and indicators, symbols used, ergonomic features, physical design and layout, hierarchy of operation, menus for a software driven MEDICAL DEVICE, visibility of warnings, audibility of an ALARM SIGNAL, standardization of color coding.

E.2.15 Is the MEDICAL DEVICE used in an environment where distractions are commonplace?

Features should be designed so that they cannot be easily misused by busy USERS in an environment where distractions are commonplace.

E.2.16 Does the MEDICAL DEVICE have connecting parts or accessories?

Factors that should be considered include the possibility of wrong connections, differentiation, similarity to other products' connections, connection force, feedback on connection integrity, and over- and under-tightening.

E.2.17 Does the MEDICAL DEVICE have a control interface?

Factors that should be considered include spacing, coding, grouping, mapping, modes of feedback, blunders, slips, control differentiation, visibility, direction of activation or change, whether the controls are continuous or discrete, and the reversibility of settings or actions.

E.2.18 How is information displayed by the MEDICAL DEVICE?

Factors that should be considered include visibility in various environments, orientation, the visual capabilities of the USER, populations and perspectives, clarity of the presented information, units, color coding, and the accessibility of critical information.

E.2.19 Is the MEDICAL DEVICE controlled by a menu?

Factors that should be considered include complexity and number of layers, awareness of state, location of settings, navigation method, number of steps per action, sequence clarity and memorization problems, and importance of control function relative to its accessibility.

E.2.20 Will the MEDICAL DEVICE be used by persons with special needs?

Factors that should be considered include the intended USER, the mental and physical abilities, skill, and training of the USER, ergonomic aspects, the environment in which it is to be used, by whom it is to be installed, and whether the PATIENT can control or influence the use of the MEDICAL DEVICE. Special attention should be paid to intended USERS with special needs such as handicapped persons, the elderly, and children. Their special needs might include assistance by another person to enable the use of the MEDICAL DEVICE. Is the MEDICAL DEVICE intended to be used by individuals with various skill levels and cultural backgrounds?

E.2.21 In what way(s) might the MEDICAL DEVICE be deliberately misused?

Factors that should be considered are: incorrect use of connectors, disabling SAFETY features or ALARM SYSTEMS, neglect of MANUFACTURERS recommended maintenance.

Even if such action is considered ABNORMAL USE, the MANUFACTURER is encouraged to investigate possible deliberate misuse and, if reasonably practicable, mitigate the connected RISKS.

E.2.22 Is the MEDICAL DEVICE intended to be mobile or portable?

Factors that should be considered are the necessary grips, handles, wheels, brakes, mechanical stability, and durability.