Product Label Symbols	Product Label Legend	Product Label Symbols	Product Label Legend
	Consult instruction for use		Use by date
	Non sterile		Do not use if package is damaged
	manufacturer	MD	Medical device
	Date of manufacture	CE	Conformité Européene
REF	Catalog number	EC REP	Authorized representative in the European Union
LOT	Batch code		

CE 1639 The CE mark is valid only if it is also printed on the product label

aZure® Implant System

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EC REP

European Authorised Representative(E.A.R): **Lotus NL B.V.**
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English

aZure Implant System Surgical Kits and Instruments

Please carefully read instructions for use prior to use.

1. Product Descriptions

The surgical instructions contained in this kit are made of medical-grade stainless steel. The surgical instruments should be stored in the surgical tray during the implantation surgery. The instruments are color-coded according to diameters and surgical protocol. This product is packaged as Non-Sterile and must be sterilized prior to use.

For detailed information on the specific procedure for the product you are using, please refer to the appropriate manual/ guide on the website www.zimmerbiometdental.com.

2. Intended use

This product is used during the placement of aZure Implant System dental implants and restorative products (including combination products such as cover screws, healing screws, abutments and other accessories).

The drill extension is used to lengthen drill shank.

The lance drill is used to drill for initial pilot hole.

The round drill is used to level bone or create initial hole.

The lindemann drill is a side cutting drill which is used to adjust a pilot osteotomy.

The twist drill is used to prepare a specific depth of osteotomy for implantation.

The implant tap (dense bone tap) may pre-thread the osteotomy with placement of implants in dense cortical bone.

The final implant drill is used to widen the osteotomy by following the appropriate drilling sequence for the implant diameter being placed. Consider the bone quality prior to selection of the final drill.

The pilot drill is used to create the pilot hole of the osteotomy.

The cortical drill is used after the twist drill to cut cortical layer and expends the osteotomy for implant placement.

The implant driver is used to pick up the implant from the packaging and driver it into the osteotomy. There are two options in order to deliver the implant by either handpiece or torque wrench.

The Hex/ Slotted driver is used to insert any restorative components.

The bone profiler is used to trim the bone surrounding the coronal aspect of the implant.

3. Indication for use

This product is indicated for use solely with the aZure Implant System.

4. Prior to Use

Clinicians should familiarize themselves with all of the instruments and tools contained within this kit, as well as read these instructions for use and all other instructions for use pertaining to the aZure Implant System prior to performing any implant-related procedures.

5. Clinical Benefits

The clinical benefits of the instruments are primarily to facilitate appropriate alignment, sizing, positioning and explanation of the associated implants.

6. Target Patient Population

Any patient who has a "hopeless" tooth (or teeth) requiring extraction or has had a tooth extracted or "lost", or has a congenitally missing tooth.

7. Warnings and Precautions

These products are packaged Non-Sterile and must be cleaned and sterilized prior to each use.

These devices are only to be used by trained professionals. The surgical and restorative techniques required to properly utilize these devices are highly specialized and complex procedures.

The kit, instruments and tools must be thoroughly cleaned, disinfected and sterilized prior to use.

Before each use, visually inspect all devices and trays/kits for completeness, damage and/or excessive wear (e.g. Corrosion or rust build-up on the instrument surface, structural wear or damage, grommet presence or damage, partial or complete fracture.)

All instruments and tools must be thoroughly inspected and cleaned prior to being replaced in the tray for disinfection and cleaning.

Do not use hydrogen peroxide-containing solution for disinfection or cleaning, as it may result in corrosion or oxidation and/or removal of laser markings.

Universal Precautions should be observed by all clinic/hospital personnel that work with contaminated or potentially contaminated medical devices. Caution should be exercised when handling devices with sharp points or cutting edges.

8. Cleaning, Disinfection and Sterilization

All reusable instruments and tools should be sterilized prior to use in patients.

Re-assemble the surgical kit necessary and place the cleaned instruments into their specific locations.

Standard medical-grade, steam sterilization wrap may be used to

package the kits and components. The package should be prepared using the AAMI double-wrap or equivalent method.
The effective period is 30 days after sterilization. If 30 days have passed since it was cleaned, disinfected, and sterilized repeat the sterilization operation before use. If the sterilization requirements of the area or country where the instruments are used are stricter than the above conditions, the more stringent requirements shall prevail.
Sterile instruments wraps should be carefully examined prior to opening to ensure that the packaging integrity has not been compromised.
Personal Protective Equipment (PPE) should be worn when handling or working with contaminated or potentially contaminated materials, devices and equipment. PPE includes gown, mask, goggles or face shield, gloves and shoe covers.
Metal brushes or scouring pads must not be used during manual cleaning procedures. These materials will damage the surface and finish of the instruments. Soft-bristled, nylon brushes and pipe cleaners should be used.
Cleaning agents with low foaming surfactants should be used during manual cleaning procedures to ensure that instruments are visible in the cleaning solution. Manual scrubbing with brushes should always be performed with the instruments below the surface of the cleaning solution to prevent generation of aerosols and splashing which may spread contaminants. Cleaning agents must be completely rinsed from device surfaces to prevent accumulation of detergent residue.
DO NOT stack instruments or place heavy instruments on top of delicate devices.
Dry, soiled surgical instruments are more difficult to clean. **DO NOT** allow contaminated devices to dry prior to reprocessing. All subsequent cleaning and sterilization steps are facilitated by not allowing blood, body fluids,bone and tissue debris, saline, or disinfectants to dry on used instruments.
Unwrapped instrument cases **DO NOT** maintain sterility.
Instruments that are able to be disassembled should be disassembled prior to cleaning and sterilization. Care must be taken o avoid losing small parts.

The following is a list of recommend sterilization parameters

Moist-heat sterilization mode	Optimal sterilization temperature	Minimally required sterility time	Minimally required drying time
Gravity placement	121℃	30 minutes	15 minutes
Vacuum type	132℃	4 minutes	20 minutes

9. Storage and Disposal
Instruments should be dried completely prior to storage. Sterile, wrapped instruments should be stored in a designated, limited access area that is well ventilated and protected from temperature and humidity extremes.
10. Adverse Reactions
Adverse events from improper use of these instruments and tools may include, but not limited to : never damage or dislocation, infection, edema, subcutaneous bleeding, pain, dismantling of structure and soft tissue ulcers.
Local allergic reactions may occur.
11. Disposal Information
All used aZure implants and instruments are a potential biohazard, since they may be contaminated with blood or other body fluids, bone or other tissue. Handle and dispose these products in accordance with accepted medical practice and with applicable local, state and national laws and regulations. Any sharp objects should be disposed of immediately after use into a sharps container conforming to EN ISO 23907-1 or equivalent following the requirements in 2010/32/EU directive or equivalent national laws. The sharp edge must not be bent or broken and should be re-sheathed prior to disposal.
12. Reporting Problems
The user and/or patient should report any suspected serious incident related to the device by informing the manufacturer and the competent authority of the member state in which the serious incident has occurred.
Storage and Handling
aZure implant system implants, abutments, and instrument should be stored at room temperature.