INSTRUCTION FOR USE Brand Name's:
BioLine

MANUFACTURER :	M.D.M Medical Devicess Manufacturing Ltd., Ha'ella 1 street Tefen industrial park p.o.b 70 zip 2495900 Israel
PRODUCT DESCRIPTION :	Threaded Dental Implants Dental Abutments Surgical Tools

1. GENERAL

1.1. Success rates of dental implants vary, depending on where in the jaw the implants are placed. However, in general, dental implants have a success rate of up to 98%. With proper care, implants can last a lifetime.

2. DISCLAIMER

2.1. SDI products are intended for use by certified dentists adequately trained in the use of SDI's products. All devices are for prescription use only!

3. INDICATIONS

3.1. Among the most common indications for undergoing a dental implantation procedure are:

3.1.1. Need for Replacement of missing teeth.

3.1.2. Supporting Removable Dentures (full or partial).

3.1.3. Securing/Supporting a bridge that replaces multiple missing teeth.

3.2. SDI's Implants are designed for prosthodontics reconstruct ion. They act as replacements of the natural root. Within a period of a few months, the Implant becomes securely attached (osseointegrated) to the bone in a manner that will allow it to withstand chewing forces and function like a natural root.

3.3. Although there are few limitations to this procedure, there are factors that contribute to the long-term success of these implants such as:

3.3.1. Bone tissue availability to receive and support the implant.

3.3.2. In cases where there is insufficient bone to provide support for the dental implants, bone grafting should be considered.

3.3.3. Quality and Choice of Abutment and Crown placed on top of the implant. The quality of the restored tooth will play an important role in the long-term success of the implantation.

4. CONTRAINDICATIONS

4.1. The Dental Implants are intended to be implanted for patients, above 13 years old

4.2. Dental implantation is a surgery operation. Any contraindication that applies to surgery operations applies to patients subject to a dental implant operation.

4.3. Hypersensitivity to components of the implant.

4.4. Inadequate bone mass.

5. DENTAL IMPLANT PROBLEMS

5.1. Patient must have a comprehensive dental examination along with an IOPA, OPG and preferably a CT scan.

5.2. Patient must get a comprehensive tailored treatment plan prepared by the dental doctor.

5.3. Patient must provide the doctor with his complete medical condition.

6. DENTAL IMPLANTATION PROBLEMS

6.1. Following is a list of the main reasons for implant problems:

6.1.1. Rejection of the implant: Due to the failure of the jawbone to osseointegrate with the implant.

6.1.2. Infection at the implant site: May be caused due to poor oral hygiene.

6.1.3. Tissue Injury and Damage : The affected area usually swells temporarily, but returns to normal within a few days.

6.1.4. Nerve damage : A painful issue, caused due to placement of the implant very close to the nerve or over the nerve. In a case like this, the patient should immediately report this to the dentist. The dentist may remove the implant (if necessary) and replace it.

6.1.5. Sinus Problems : May happen in upper jaw implantation when dental implant protrudes into one of the sinuses. To address this issue, the dentist might replace the implant.

6.1.6. Immediate loading : Some dentists prefer building the crown on top of the implant immediately after the implantation. This being done, the forces exerted on the implant might disturb the osseointegration process and cause dental implant failure.

7. POSSIBLE UNDESIRABLE SIDE EFFECTS

7.1. Possible undesirable side effects associated with dental implants include:

7.1.1. Bleeding, Short term swelling and bruising of the gums and face, local pain, Infection, Nerve damage, Jaw Fracture.

8. POST-SURGERY ORAL HYGIENE AND CARE OF IMPLANTS

8.1. The patient should be aware of adopting and maintaining good oral hygiene to avoid infections.

8.2. The implant should be treated like a natural tooth.

8.3. Teeth should be brushed at least twice a day and flossed once a day.

8.4. The patient has to maintain a habit of periodical visits to the doctor's office for inspection and professional cleaning.

8.5. During routine checks at the dentist, the implant will be checked for any signs of wear and tear.

9. PROCEDURAL PRECAUTIONS

9.1. Thorough screening of prospective implant candidates must be performed. A systematic and coordinated plan delineating the responsibilities of each member of the operation team should be developed and followed.

9.2. The evaluation of implantation patients should include the following steps:

9.2.1. Elicit and record a comprehensive medical and dental history of the patient and consider the relevance of that information to the individual case. 9.2.2. Perform a comprehensive visual inspection as well as panoramic and apical radiographs in order to determine anatomical landmarks, occlusal conditions, periodontal status, and adequacy of the bone.

9.2.3. Lateral cephalometric radiographs and tomograms may also be beneficial in special cases.

9.3. During the planning phase it is important to determine the availability of adequate bone mass for implant placement and to confirm that the available occlusal space is sufficient to accommodate the proposed abutment and final restoration. Minimizing the trauma to the host tissue increases the potential for successful osseointegration.

9.4. CAUTION : Electro-surgery should not be attempted around metal implants, as they are conductive.

IMPLANTS

1. General

1.1 Storage and Handling : Unless otherwise specified on product's package, label or corresponding manual, devices should be stored at room temperature.

1.2 Sterilization : All Implants have undergone a sterilization process performed by an appropriate validated method. Refer to individual product labels for sterilization information. All sterile implants are labeled "STERILE".

1.3 Warnings

1.0.1. All sterile implants are for single use only.

1.0.2. They should not be re-sterilized.

1.0.3. All sterile implants must not be used after the expiration date printed on the product label.

1.0.4. Sterile implants must not be used if the package has been damaged or previously opened.

1.4 Each Implant is individually packed in a package.

1.5 Sterilization of the entire content of the package is achieved by Gamma Ray irradiation as the last production step prior to delivery. The sterilization is ensured for a period of 5 years by the tightness of the package.

1.6 The open blister shows two distinct compartments.

1.7 One holds 2 copies of the traceability sticker.

1.8 The second compartment holds a Polystyrene Crystal Vial with the Implant inside it.

1.9 Sterility of the implant is assured as long as the lid was not pulled off.

1.10 The implant is kept in place by being inserted into a cylindrical pocket in the lid of the vial.

1.11 By pulling the lid out of the vial, the implant is exposed for further operations.

2. Implant Types

2.1 SDI - Spiral Dental Implant
2.2 CSI - Spiral Cone Dental Implant
2.3 CDI - Cylindrical Dental Implant

Please refer to SDI literature (catalogs, user-guide, research, etc.).

DRILLING SEQUENCES FOR ALL BONE TYPES

Type	Implant Diameter	I	II	III	IV
SDI CDI	Ø **3.3 mm**	Marking Drill Ø 2.00 mm Ø 2.80 mm Ø 3.20 mm	Marking Drill Ø 2.00 mm Ø 2.80 mm Ø 3.20 mm	Marking Drill Ø 2.00 mm Ø 2.80 mm	Marking Drill Ø 2.00 mm Ø 2.80 mm

Type	Implant Diameter	I	II	III	IV
CSI CDI	Ø 3.75 mm	Marking Drill Ø 2.00 mm Ø 2.80 mm Ø 3.20 mm Ø 3.65 mm	Marking Drill Ø 2.00 mm Ø 2.80 mm Ø 3.20 mm Ø 3.65 mm	Marking Drill Ø 2.00 mm Ø 2.80 mm Ø 3.20 mm	Marking Drill Ø 2.00 mm Ø 2.80 mm Ø 3.20 mm

Type	Implant Diameter	I	II	III	IV
SDI CSI CDI	Ø 4.20 mm	Marking Drill Ø 2.00 mm Ø 2.80 mm Ø 3.20 mm Ø 3.65 mm Ø 4.20 mm	Marking Drill Ø 2.00 mm Ø 2.80 mm Ø 3.20 mm Ø 3.65 mm Ø 4.20 mm	Marking Drill Ø 2.00 mm Ø 2.80 mm Ø 3.20 mm Ø 3.65 mm	Marking Drill Ø 2.00 mm Ø 2.80 mm Ø 3.20 mm Ø 3.65 mm

Type	Implant Diameter	I	II	III	IV
SDI CSI CDI	Ø 5.00 mm	Marking Drill Ø 2.00 mm Ø 2.80 mm Ø 3.20 mm Ø 3.65 mm Ø 4.20 mm Ø 5.20 mm	Marking Drill Ø 2.00 mm Ø 2.80 mm Ø 3.20 mm Ø 3.65 mm Ø 4.20 mm Ø 5.20 mm	Marking Drill Ø 2.00 mm Ø 2.80 mm Ø 3.20 mm Ø 3.65 mm Ø 4.20 mm	Marking Drill Ø 2.00 mm Ø 2.80 mm Ø 3.20 mm Ø 3.65 mm Ø 4.20 mm

Type	Implant Diameter	I	II	III	IV
SDI CSI CDI	Ø 6.00 mm	Marking Drill Ø 2.00 mm Ø 2.80 mm Ø 3.20 mm Ø 3.65 mm Ø 4.20 mm Ø 5.20 mm	Marking Drill Ø 2.00 mm Ø 2.80 mm Ø 3.20 mm Ø 3.65 mm Ø 4.20 mm Ø 5.20 mm	Marking Drill Ø 2.00 mm Ø 2.80 mm Ø 3.20 mm Ø 3.65 mm Ø 4.20 mm Ø 5.20 mm	Marking Drill Ø 2.00 mm Ø 2.80 mm Ø 3.20 mm Ø 3.65 mm Ø 4.20 mm Ø 5.20 mm

ABUTMENTS

1. General

1.1 Storage and Handling : Unless otherwise specified on product's package, label or corresponding manual, devices should be stored at room temperature.

1.2 Sterilization : Abutments are not provided in sterilized condition and are marked so.

1.3 Abutments are made of Titanium, Zirconia, Peek (for casting only).

1.4 Abutments are oriented with the Implant via a Male / Female Hexagon fit.

1.5 Attachment of the Abutment to the Implant is secured by a 1-72 UNF Titanium screw which is included within the package of each abutment. The predetermined tightening torque of the screw is achieved by using SDI torque wrench.

2. Abutment Types

1.6 SDI's Abutments are provided in basically two types of abutments: Straight and Angular. The standard inclination angles of the angular abutments are 15° and 25°.

1.7 Each Abutment type is available in Standard or Anatomic configurations with Neck heights of 1.00, 2.00, 3.00 and 4.00 mm.

1.8 All Abutments are Compatible with all Implants having a 3.75 mm diameter platform.

SURGICAL TOOLS

1. Cleaning

1.1 Used instruments should be soaked immediately in instrument cleaning solution
to avoid the drying of blood, saliva and tissue residue. Used surgical cases including grommets must be cleaned with suitable disinfectants.

1.2 Multiple-part instruments must be disassembled prior to cleaning and sterilization.
Internal debris/residue of instruments must be removed with a soft hair brush.

1.3 Instruments should be visually inspected, cleaned separately and discarded if damaged.

1.4 Best results are achieved if surgical instruments are cleaned categorized by the material type they are made of.

1.5 Instruments and cases can be cleaned and disinfected in a dedicated dishwasher or alternatively by hand, followed by an ultrasonic bath with a detergent appropriate for surgical instruments.

1.6 Instruments and cases must be rinsed and dried thoroughly.

2. Sterilization of Surgical Tools

1.7 Clinically contaminated implants should not be cleaned and re-sterilized under any circumstances.

1.8 Do not autoclave hard plastic items, which can melt at approximately 338°F (170°C). Cold sterilize these items according to manufact urer's recommendations then rinse thoroughly with sterile distilled water.

1.9 Proper maintenance of surgical tools is extremely important. Damage to drill tips can cause significant impairment of drill function. Following are detailed instructions for proper maintenance.

3. **Instructions for Maintenance of Surgical Tools**

1.10 Maintenance of Surgical Tools Prior to First Time use

3.0.1. Stage 1 - Light Cleaning and Rinsing

3.0.1.1. Surgical tools should be dipped in detergent, rinsed, and dried.

3.0.2. Stage 2 – Sterilization

3.0.2.1. Drills should be sterilized in an autoclave at 135 ° C /275° F for up to a minimum of 3 minutes and maximum of 5 minutes.

1.11 Cleaning and Storage of Surgical Tools after use

3.0.3. Stage 1 - Cleaning

3.0.3.1. Surgical tools should be brushed with detergent to remove any remaining blood or tissue.

3.0.4. Stage 2 - Ultrasonic Cleaning

3.0.4.1. Surgical tools should be cleaned in an ultrasonic bath using an appropriate detergent. During ultrasonic cleaning, contact between surgical tools must be avoided.

3.0.5. Stage 3 – Rinsing

3.0.5.1. Surgical tools should be rinsed under running water and dried.

3.0.6. Stage 4 – Lubrication (This is obligatory if more than 4 weeks of storage is expected)

3.0.6.1. Surgical tools should be soaked in dental oil for 10 seconds, then removed from solution and left to dry for 30 seconds without rinsing or towel drying. When done, Tools have to be placed in a surgical kit.

3.0.7. Stage 5 – Sterilization

3.0.7.1. Surgical tools should be sterilized in an autoclave at 135ºC/275ºF for a minimum of 3 minutes.

3.0.8. Stage 6 – Storage

3.0.8.1. At this stage, kits are ready for long-term storage; they can be used immediately upon opening the kit.

1.12 Recommendations

3.0.9. Cutting tools should be used for a maximum of 30 cycles. Distilled water should be used in order to avoid surface stains

1.13 Storage

3.0.10. Implant devices should be kept at room temperature. For special instructions referring to optimal preservation and treatments, refer to each product's label.

KEY TO CODES USED

	Expiration date (use by)		Single use - Do not reuse
	Consult operating instructions		Date of manufacture
	Do not use if sterile package is compromised		Manufacturer
STERILE R	Sterilized using irradiation	NON STERILE	Non-Sterile
EC REP	Authorised Representative in the european Community	REF	Catalogue No.
LOT	Batch code / Number	CE	CE-Mark symbol

Storage and Handling

Dental Implants must be stored in a dry location at room temperature, in their original packaging.

Dental Implants are packaged suspended in sterile vials. Do not handle implant surfaces directly.

Users are advised to visually inspect vials to insure seals and contents are intact and in their original packaging prior to use.

For more details on the indications and handling of the SDI dental implants system, please refer to SDI literature (catalogs, user-guide, research, etc.).

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