

Instructions for Use

Reflect™ Implant System Fixtures and Prosthetics

Caution: Federal law restricts this device for sale, to or on the order of, a licensed dentist or physician.

Implant Lines

- Reflect Aspire Implant Fixtures and Prosthetics
- Reflect Certus Implant Fixtures and Prosthetics
- Reflect Rapid Implant Fixtures and Prosthetics
- Reflect Recover Implant Fixtures and Prosthetics
- Reflect Tapered Implant Fixtures and Prosthetics

1. Product Summary

The Reflect™ Implant System is designed for the attachment of removable or permanent, partial or complete, prosthodontic appliances. Implant osseointegration, which occurs after healing, provides a physiologic replacement for lost dentition. Reflect™ Implants are dental implants which are made of pure titanium, and are surgically implanted into the mandible (the lower jaw bone), or the maxilla (the upper bone) to restore chewing function of partially or fully edentulous patients. There are various sizes and shapes of implants to accommodate anterior or posterior conditions of dental loss.

2. Indications for Use

Reflect™ Dental Implants are indicated for use in partially or fully edentulous patients to support maxillary and mandibular single-unit, multiple-unit, and overdenture dental restorations. Reflect™ Dental Implants are indicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

Reflect™ Implant System prosthetic components are compatible with the following implant systems.

| Implant System Compatibility | Implant Body Diameter (mm) | Platform Diameter (mm) |
|------------------------------|----------------------------|------------------------|
| OsseoSpeed™ | 3.5 | 3.5/4.0 |
| | 4.0 | 3.5/4.0 |
| | 5.0 | 4.5/5.0 |
| 3i Certain® | 3.25 | 3.4 |
| | 4.0 | 4.1 |
| | 5.0 | 5.0 |
| NobelActive® | 3.5 | NP |
| | 4.3 | RP |
| | 5.0 | RP |
| NobelReplace Conical | 3.5 | NP |
| | 4.3 | RP |
| | 5.0 | RP |
| Tapered Screw-Vent® | 3.7 | 3.5 |
| | 4.1 | 3.5 |
| | 4.7 | 4.5 |

3. Precautions

Adequate palpation and direct visual inspection of the prospective implant site are necessary to determine anatomy of available bone. The location of anatomical features to be avoided should be established prior to the use of dental implants. The patient should demonstrate bone dimension adequate to accommodate the implant. In selecting implant size, dimensional consideration is necessary to avoid complications.

4. Warnings

Surgical techniques required to place dental implants are highly specialized and complex procedures. Specialized training is strongly recommended. Practitioners should attend courses of study to prepare them in established techniques of oral implantology. Improper technique can cause implant failure and loss of bone. Dental implant systems are intended to be used only with the specially-designed bone drills, supplied with the surgical kit and corresponding prosthetic abutments. Excessive mobility, bone loss, or infection may indicate the implant is failing. Any implant which is failing should be removed as soon as possible. If removal is necessary, curette the soft tissue from the implant site and allow the site to heal as though it were an atraumatic extraction.

NOTE:

The Reflect Implant System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of Reflect Implant System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

5. Contraindication

Implants should not be placed if there is insufficient alveolar bone width and height to surround the implant. Implants should not be used in patients where ridge dimensions are insufficient to accommodate proper implant placement. Insufficient availability of bone, poor bone quality, poor patient oral hygiene, heavy smoking or use of chewing tobacco, and generalized diseases (diabetes, etc.) may contribute to lack of osseointegration and subsequent implant failure. Severe bruxism or overloading may cause failure of the implants or abutments. Contraindications ordinary to oral surgery should be observed. These include, but are not limited to: significant vascular impairment to the implant site, metabolic bone disease, clotting disorders, concurrent treatment with therapeutic agents which may have an effect on the surgical site, the surrounding tissue or normal biological healing responses (i.e., drug therapy, radiation therapy, etc.), and uncontrolled diabetes or other metabolic or systemic disorders which affect bone or wound healing.

Small diameter implants and angled abutments are not recommended for use in the posterior region of the mouth.

6. Adverse Effects

The following surgical procedure-related complications may occur: dehiscence, delayed healing, paresthesia, hyperesthesia, edema, hematoma, infection, inflammation, and local and generalized allergic reaction. Numbness from nerve damage in the facial area is usually a temporary symptom, but in some cases it is permanent. The selection of an unsuitable implant (diameter, length) or the inadequate creation of the insertion hole can result in implant failure due to bone loss, low initial stability, or osseointegration failure.

7. Instruction for Use & Procedure

Anterior and posterior locations can be treated following the standard surgical protocol. Prosthetic and laboratory components are to be utilized with this system following the standard protocol for the construction of the dental prosthesis in the given clinical situation. Indications include single-tooth restoration, multi-unit restoration, implant supported partial denture, implant supported bar overdenture, implant retained overdenture, fixed-detachable implant prosthesis and totally edentulous implant retained prosthetic designs.

Multiple implant diameters are designed for different available bone widths in the treatment areas. If a larger diameter implant can be utilized, it is recommended that it be used to engage the greatest amount of bone volume.

Sterilization: Reflect™ Implants and healing abutments are provided sterile. Abutments not provided sterile must be steam sterilized with a gravity cycle of 121 °C/250 °F for 30 minutes with a 30 minute dry time using an FDA cleared sterilization wrap.

8. Preservation & Handling

The implant package is hermetically sealed and sterilized with gamma radiation and should be stored at low humidity and room temperature. The product must be opened just prior to surgery. Only surgical instruments verified for use with medical devices should be used.

Tightening Torque Values

| Abutment | Abutment Screw | Compatible Reflect Implants | Compatible OEM Implants | Tightening Torque, Ncm |
|--------------------------------------|--------------------------|--|--|------------------------|
| Reflect Aspire | | | | |
| Aspire Cover Screw Ø 3.5 mm | NA | Reflect Aspire Body Ø 3.5 mm Platform Ø 3.5 mm | Astra Tech OsseoSpeed™ Body Ø 3.5 mm Platform Ø 3.5/4.0 mm | 5-10 |
| Aspire Ø 3.5/4.0 mm Healing Abutment | NA | | | 5-10 |
| Aspire Ø 3.5 mm 30° Abutment | Aspire Screw 3.5/4.0 | | | 35 |
| Aspire Cover Screw Ø 4.0 mm | NA | Reflect Aspire Body Ø 4.0 mm Platform Ø 4.0 mm | Astra Tech OsseoSpeed™ Body Ø 4.0 mm Platform Ø 3.5/4.0 mm | 5-10 |
| Aspire Ø 3.5/4.0 mm Healing Abutment | NA | | | 5-10 |
| Aspire Ø 4.0 mm 30° Abutment | Aspire Screw 3.5/4.0 | | | 35 |
| Aspire Cover Screw Ø 5.0 mm | NA | Reflect Aspire Body Ø 5.0 mm Platform Ø 5.0 mm | Astra Tech OsseoSpeed™ Body Ø 5.0 mm Platform Ø 4.5/5.0 mm | 5-10 |
| Aspire Ø 4.5/5.0 mm Healing Abutment | NA | | | 5-10 |
| Aspire Ø 5.0 mm 30° Abutment | Aspire Screw 4.5/5.0 | | | 35 |
| Reflect Certus | | | | |
| Certus Cover Screw Ø 3.4 mm | NA | Reflect Certus Body Ø 3.4 mm Platform Ø 3.4 mm | Biomet 3i Certain® Body Ø 3.25 mm Platform Ø 3.4 mm | 10 |
| Certus Ø 3.4 mm Healing Abutment | NA | | | 20 |
| Certus Ø 3.4 mm 30° Abutment | Certus Screw 3.4/4.1/5.0 | | | 20 |
| Certus Cover Screw Ø 4.1 mm | NA | Reflect Certus Body Ø 4.1 mm Platform Ø 4.1 mm | Biomet 3i Certain® Body Ø 4.0 mm Platform Ø 4.1 mm | 10 |
| Certus Ø 4.1 mm Healing Abutment | NA | | | 20 |
| Certus Ø 4.1 mm 30° Abutment | Certus Screw 3.4/4.1/5.0 | | | 20 |
| Certus Cover Screw Ø 5.0 mm | NA | Reflect Certus Body Ø 5.0 mm Platform Ø 5.0 mm | Biomet 3i Certain® Body Ø 5.0 mm Platform Ø 5.0 mm | 10 |
| Certus Ø 5.0 mm Healing Abutment | NA | | | 20 |
| Certus Ø 5.0 mm 30° Abutment | Certus Screw 3.4/4.1/5.0 | | | 20 |
| Reflect Rapid | | | | |
| Rapid Cover Screw NP | NA | Reflect Rapid Body Ø 3.5 mm Platform NP (Ø 3.5 mm) | NobelActive® and NobelReplace Conical Body Ø 3.5 mm Platform NP | 5-10 |
| Recover/Rapid NP Healing Abutment | NA | | | 10-20 |
| Rapid NP 30° Abutment | Recover/Rapid Screw NP | | | 35 |
| Rapid Cover Screw RP | NA | Reflect Rapid Body Ø 4.3 mm Platform RP (Ø 3.9 mm) | NobelActive® and NobelReplace Conical Body Ø 4.3 mm Platform RP | 5-10 |
| Recover/Rapid RP Healing Abutment | NA | | | 10-20 |
| Rapid RP 30° Abutment | Recover/Rapid Screw RP | | | 35 |
| Rapid Cover Screw RP | NA | Reflect Rapid Body Ø 4.3 mm Platform RP (Ø 3.9 mm) | NobelActive® and NobelReplace Conical Body Ø 5.0 mm Platform RP | 5-10 |
| Recover/Rapid RP Healing Abutment | NA | | | 10-20 |
| Rapid RP 30° Abutment | Recover/Rapid Screw RP | | | 35 |

| Abutment | Abutment Screw | Compatible Reflect Implants | Compatible OEM Implants | Tightening Torque, Ncm |
|-----------------------------------|------------------------|--|---|------------------------|
| Reflect Recover | | | | |
| Recover Cover Screw NP | NA | Reflect Recover Body Ø 3.5 mm Platform NP (Ø 3.5 mm) | NobelActive® and NobelReplace Conical Body Ø 3.5 mm Platform NP | 5-10 |
| Recover/Rapid NP Healing Abutment | NA | | | 10-20 |
| Recover NP 30° Abutment | Recover/Rapid Screw NP | | | 35 |
| Recover Cover Screw RP | NA | Reflect Recover Body Ø 4.3 mm Platform RP (Ø 3.9 mm) | NobelActive® and NobelReplace Conical Body Ø 4.3 mm Platform RP | 5-10 |
| Recover/Rapid RP Healing Abutment | NA | | | 10-20 |
| Recover RP 30° Abutment | Recover/Rapid Screw RP | | | 35 |
| Recover Cover Screw RP | NA | Reflect Recover Body Ø 5.0 mm Platform RP (Ø 3.9 mm) | NobelActive® and NobelReplace Conical Body Ø 5.0 mm Platform RP | 5-10 |
| Recover/Rapid RP Healing Abutment | NA | | | 10-20 |
| Recover RP 30° Abutment | Recover/Rapid Screw RP | | | 35 |
| Reflect Tapered | | | | |
| Tapered Cover Screw Ø 3.5 mm | NA | Reflect Tapered Body Ø 3.7 mm Platform Ø 3.5 mm | Tapered Screw-Vent® Body Ø 3.7 mm / Platform Ø 3.5 mm Body Ø 4.1 mm / Platform Ø 3.5 mm | 5-10 |
| Tapered Ø 3.5 mm Healing Abutment | NA | | | 10-20 |
| Tapered Ø 3.5 mm 30° Abutment | Tapered Screw 3.5/4.5 | | | 35 |
| Tapered Cover Screw Ø 3.5 mm | NA | Reflect Tapered Body Ø 4.1 mm Platform Ø 3.5 mm | Tapered Screw-Vent® Body Ø 4.7 mm Platform Ø 4.5 mm | 5-10 |
| Tapered Ø 3.5 mm Healing Abutment | NA | | | 10-20 |
| Tapered Ø 3.5 mm 30° Abutment | Tapered Screw 3.5/4.5 | | | 35 |
| Tapered Cover Screw Ø 4.5 mm | NA | Reflect Tapered Body Ø 4.7 mm Platform Ø 4.5 mm | Tapered Screw-Vent® Body Ø 6.0 mm Platform Ø 5.7 mm | 5-10 |
| Tapered Ø 4.5 mm Healing Abutment | NA | | | 10-20 |
| Tapered Ø 4.5 mm 30° Abutment | Tapered Screw 3.5/4.5 | | | 35 |



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Symbols Glossary

ANSI/AAMI/ ISO 15223-1:2012 Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements.

| Symbol | Title of Symbol (Reference Number) |
|----------------|--|
| i | Consult Instructions for Use (5.4.3) |
| | Caution: Consult accompanying documents (5.4.4) |
| | Manufacturer (5.1.1) |
| | Date of manufacture (5.1.3) |
| | Use-by date (5.1.4) |
| | Batch code (5.1.5) |
| | Catalogue number (5.1.6) |
| | Serial number (5.1.7) |
| | Sterilized using irradiation (5.2.4) |
| | Do not re-use (5.4.2) |
| | Do not re-sterilize (5.2.6) |
| | Do not use if package is damaged (5.2.8) |
| | Temperature limitation (5.3.7) |
| Rx Only | For USA Only (Federal law(USA) restricts this device to sale by or on the order of a licensed dentist) |
| | CE conformity marking |
| | Authorized representative in the European community (5.1.2) |