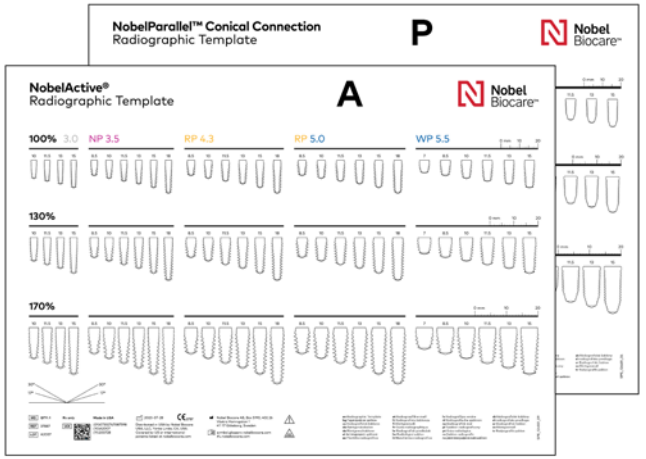
Radiographic Templates
Instructions for Use



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Please note that some products detailed in this Instruction for Use may not be regulatory cleared, released or licensed for sale in all markets.

Description:

Traditional 2-dimensional (2D) radiographic imaging (X-ray) of dental implant sites typically involves the use of periapical radiographs for single implant sites, and panoramic radiographs for fully edentulous patients and multiple implant sites. Radiographic templates can be used in combination with such X-rays to support 2D dental implant surgical and prosthetic planning.

The templates consist of a transparent overlay which present the silhouette and dimensions of each implant in a given Nobel Biocare implant family, in magnification factors of 100%, 130% and 170% according to the magnification of the source X-ray. The templates are placed over the subject X-ray to evaluate the potential fit of different implant types and dimensions, with respect to important anatomical structures such as nerves, sinuses, and neighboring roots, available bone volume, or other features or characteristics.

Radiographic templates also include the following information specific for the implant family, as well as other information useful for surgical or prosthetic planning:

- Measurement scales from 0-20 mm for the different magnification factors.
- Angulation scales of 17° and 30° for abutment selection.

All dimensions presented in the template are in millimeters and have a degree of accuracy of ± 0.5 mm.

Radiographic templates are available for the following Nobel Biocare implants (Table 1); refer to the referenced Instructions for Use (IFU) for information regarding the associated implant. These IFU are available for download at ifu.nobelbiocare.com.

Table 1: Available Radiographic Templates and Associated Implants

Radiographic Template	Implant	IFU
Brånemark System® / NobelSpeedy Radiographic Template	Brånemark System® Mk III Brånemark System® Mk III TiUnite™ NobelSpeedy® Groovy	IFU1014 IFU1015
NobelReplace® Tapered Radiographic Template	NobelReplace® Tapered Replace Select Tapered	IFU1010
NobelSpeedy® Groovy Radiographic Template	NobelSpeedy® Groovy	IFU1007
NobelParallel™ CC Radiographic Template	NobelParallel™ CC TiUnite™ NobelParallel™ CC TiUltra™	IFU1002 IFU1078
NobelActive® Radiographic Template	NobelActive® TiUnite NobelActive® TiUltra	IFU1001 IFU1076
Replace Select™ TC Radiographic Template	Replace Select™ TC	IFU1008
Nobel Biocare N1™ Radiographic Template	Nobel Biocare N1™	IFU1087

Intended Use / Intended Purpose:

Intended for use as an aid during dental implant surgical and prosthetic planning to support selection of the appropriate implant type, dimensions, placement location, and orientation.

Indications:

Same as Intended Use/Intended Purpose.

Contraindications:

There are no contraindications for the radiographic templates. For contraindications specific to the implants, refer to the Nobel Biocare IFU for the implant (see Table 1).

Warnings:

When an implant needs to be placed in proximity to a vital structure, such as a nerve, artery, or sinus cavity, a 2D radiographic imaging provides only basic information about the possible implant position.

Cautions:

General:
Do not make any reproductions of the radiographic template. Inaccuracies or distortions in the images may occur if the radiographic template is copied or scanned.

Intended Users and Patient Groups:

Radiographic templates are to be used by dental health care professionals only. Radiographic Templates are never in contact with patients.

Clinical Benefits and Undesirable Side Effects:

Clinical Benefits Associated with Radiographic Templates:
Radiographic Templates are components of treatment with a dental implant system and/or dental crowns and bridges. As a clinical benefit of treatment, patients can expect to have their missing teeth replaced and/or crowns restored.

Undesirable Side Effects Associated with Radiographic Templates:
None known.

Notice regarding serious incidents:

For a patient/user/third party in the European Union and in countries with an identical regulatory regime (Regulation 2017/745/EU on Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and to your national authority. The contact information for the manufacturer of this device to report a serious incident is as follows:

Nobel Biocare AB
https://www.nobelbiocare.com/complaint-form

Handling Procedure:

Warning: Inspect the radiographic template before each use for evidence of deterioration such as deformation, illegible or faded images, discoloration, or pitting, and properly discard any templates that fail the inspection.

1. Identify appropriate calibration markers in the source X-ray (such as ball-bearing spheres of a known diameter) to estimate the respective magnification factor (100%, 130%, or 170%) to be used and to estimate the maximum height and mesiodistal width of implant sites.
2. Place the radiographic template over the X-ray. Taking into account the magnification factor determined in Step 1, align the image of the desired implant(s) over the implant site(s) on the X-ray in order evaluate which size of implant is suitable, and how the implant can be placed.

Warning: Although this approach enables the clinician to rapidly visualize potential implant sites, it provides little information with regard to the buccal-lingual bone width or bone density. In addition, these methods of implant planning are also subject to angulation discrepancies between the planned implant position, where the radiograph indicates there is adequate bone volume, and the resultant implant site.

Caution: The OsseoDirector, OsseoShaper, Twist Drills and Twist Step Drills preparation extends up to 1 mm longer than the implant when seated. Allow for this additional length when drilling near vital anatomical structures. Refer to the IFU for the dental implant for more information regarding the drilling protocol.

Materials:

Radiographic Templates: Polycarbonate LEXAN 8010 Film with a polyethylene film on one side. Print: UV durable ink.

Sterility and Reusability Information:

Radiographic Templates: are used in the dental office only (not intended for intraoral use) and have no cleaning and/or sterilization requirements.

Warning: Inspect the radiographic template before each use for deterioration such as deformation, illegible or faded images, discoloration, or pitting, and properly discard any templates that fail the inspection.

Performance Requirements and Limitations:

To achieve the desired performance, radiographic templates must only be used with the products described in this Instructions for Use and/or in the Instructions for Use for other compatible Nobel Biocare products, and in accordance with the Intended Use for each product. To confirm the compatibility of products which are intended to be used in conjunction with radiographic templates, check the color coding, dimensions, lengths, connection type and/or any direct marking as applicable on the products or product labeling.

Facilities and Training:

It is strongly recommended that new and experienced users of Nobel Biocare products always go through special training before using a new product for the first time. Nobel Biocare offers a wide range of courses for various levels of knowledge and experience. For more information please visit www.nobelbiocare.com.

Storage, Handling and Transportation:

The device must be stored and transported in dry conditions in the original packaging at room temperature and not exposed to direct sunlight. Incorrect storage and transportation may influence device characteristics leading to failure.

Disposal:

Safely discard potentially contaminated or no longer usable medical devices as healthcare (clinical) waste in accordance with local healthcare guidelines, country and government legislation or policy.

Separation, re-cycling or disposal of packaging material shall follow local country and government legislation on packaging and packaging waste, where applicable.

Manufacturer and Distributor Information:

Manufacturer:
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CE 2797
CE Mark for
Class Im Devices

Note: Refer to the product label to determine the applicable CE mark for each device.

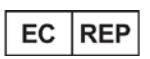
Basic UDI-DI Information:

The following table lists the Basic UDI-DI information for the devices described in this IFU.

Product	Basic UDI-DI Number
Radiographic Templates	07332747000001737A

Symbols Glossary:

The following symbols may be present on the device labeling or in information accompanying the device. Refer to the device labeling or accompanying information for the applicable symbols.



Authorized Representative in the European Community / European Union

Batch code

Catalogue number


Caution


CE mark

CE mark with Notified Body number


Consult instructions for use


Contains hazardous substances

Contains or presence of DEHP phthalate

Contains or presence of natural rubber latex

Contains or presence of phthalate

Date


Date of manufacture

Do not resterilize

Do not re-use


Do not use if package is damaged

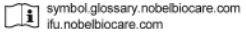

Double sterile barrier system

Rx only
For prescription use only


Health care centre or doctor


Keep away from sunlight


Keep dry



Link to Online Symbols Glossary and IFU Portal

Magnetic resonance conditional

Magnetic resonance safe


Manufacturer

Medical device


Non-pyrogenic

Non-sterile


Patient identification


Patient information website


Patient number

Serial number


Single sterile barrier system


Single sterile barrier system with protective packaging inside


Single sterile barrier system with protective packaging outside

Sterilized using Ethylene Oxide

Sterilized using irradiation

Sterilized using steam or dry heat


Temperature limit


Tooth number

Unique Device Identifier

Upper limit of temperature

Use-by date