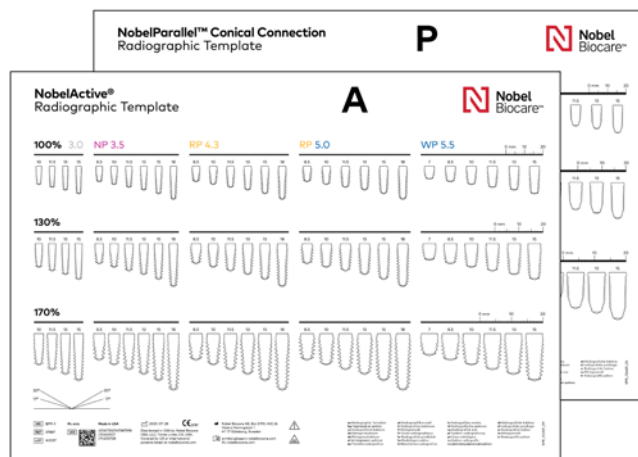


Radiographic Templates

Instructions for Use



Important – Disclaimer of Liability:

This product is part of an overall concept and may only be used in conjunction with the associated original products according to the instructions and recommendation of Nobel Biocare. Non-recommended use of products made by third parties in conjunction with Nobel Biocare products will void any warranty or other obligation, express or implied, of Nobel Biocare. The user of Nobel Biocare products has the duty to determine whether or not any product is suitable for the particular patient and circumstances. Nobel Biocare disclaims any liability, express or implied, and shall have no responsibility for any direct, indirect, punitive or other damages, arising out of or in connection with any errors in professional judgment or practice in the use of Nobel Biocare products. The user is also obliged to study the latest developments in regard to this Nobel Biocare product and its applications regularly. In cases of doubt, the user has to contact Nobel Biocare. Since the utilization of this product is under the control of the user, they are his/her responsibility. Nobel Biocare does not assume any liability whatsoever for damage arising thereof.

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 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.

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).

None identified.

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:

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.

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.

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:
Nobel Biocare AB
Box 5190, 402 26
Västra Hamngatan 1
411 17 Göteborg
Sweden
www.nobelbiocare.com

Notice Regarding Canadian Device Licensure: Note that not all products described in this IFU may have been licensed in accordance with Canadian law.

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



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



CE mark



CE mark with Notified Body number



Consult instructions for use



Contains hazardous substances



Tooth number



Unique Device Identifier



Upper limit of temperature



Use-by date



Contains or presence of DEHP phthalate



Contains or presence of natural rubber latex



Contains or presence of phthalate



Date

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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

[symbol.glossary.nobelbiocare.com](https://www.nobelbiocare.com/symbol-glossary)
[ifu.nobelbiocare.com](https://www.nobelbiocare.com/ifu)

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