Nobel Biocare Replacement Parts
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, it is his/her responsibility. Nobel Biocare does not assume any liability whatsoever for damage arising thereof. Please note that some products detailed in this Instructions for Use may not be regulatory cleared, released or licensed for sale in all markets.

Description:

Replacement parts are defined as prosthetic components and instruments in the Nobel Biocare product range that are essential to maintain existing prosthetic constructions in patients with phased-out implants i.e. implants no longer placed on the market.

Nobel Biocare replacement parts and components are divided into the following categories based on their use.

NobelPerfect® System:

- Instruments for restorative procedures: impression copings, implant replicas.
- Final restorative components: abutments.
- Temporary restorative components: healing abutments.

Brånemark System® Novum:

- Instruments for restorative procedures: implant replicas.

Brånemark System®:

- Temporary prosthetic components: healing caps.
- Final restorative components: abutments, ball attachment housings (Plastic Caps with O-ring).

Steri-Oss™ and Replace™ External Hex:

- Temporary restorative components: temporary copings.
- Final restorative components: abutments.

Immediate Provisional Implant (IPI):

- Temporary components: copings and caps.

Intended use:

NobelPerfect® System:

- Impression copings are premanufactured devices to be directly connected to the implant and used to transfer the location and orientation of dental implants, via a closed or open tray impression technique from the patients upper or lower jaw to a working dental laboratory model (master cast) together with an implant replica.
- The laboratory components such as implant replicas are intended to be used in the dental laboratory on the master cast only. Laboratory screws are used for temporary fixation of the abutments on the implant replicas.
- Dental implant abutments* are intended to be used in the upper or lower jaw for supporting tooth replacements to restore chewing function.
- Healing abutments* are intended to be used as temporary components to an endosseous implant to allow healing of the soft tissue.

Brånemark System® Novum:

- The laboratory components such as the implant replicas are intended to be used in the dental laboratory on the master cast only. Laboratory screws are used for temporary fixation of the abutments on the implant replicas.

Brånemark System®:

- Healing caps are intended to be used as a temporary component to allow healing of the soft tissue.
- Dental implant abutments* are intended to be used in the upper or lower jaw for supporting tooth replacements to restore chewing function.
- The Plastic Caps with O-ring are intended to be used in the upper or lower jaw and used for supporting tooth replacements to restore chewing function.

Steri-Oss™ and Replace™ External Hex:

- Temporary copings* are intended to be used in the upper or lower jaw for supporting tooth replacements to restore chewing function.
- Dental implant abutments* are intended to be used in the upper or lower jaw for supporting tooth replacements to restore chewing function.

Immediate Provisional Implant (IPI):

- The caps* are intended to be used as a temporary component to allow healing of the soft tissue.
- The copings* are intended to be used in the upper or lower jaw for supporting tooth replacements to restore chewing function.

** Class II device; see applicable CE Mark (CE 0086)*

Indications:

NobelPerfect® System:

- The impression copings and laboratory components do not specify a disease, condition or population and therefore the Indication for Use is the same as the Intended Use.
- Dental implant abutments in combination with two-stage endosseous implants are used as the foundation for anchoring tooth replacement in either jaw. Restorations range from replacing one single tooth to fixed partial and full dentures using cement-retained or screw-retained supra-constructions.
- The healing abutments are premanufactured prosthetic components to be directly connected to the endosseous dental implants or abutments and are indicated as temporary components for one single tooth to full arch denture procedures.

Brånemark System® Novum:

- Laboratory components such as implant replicas do not specify a disease, condition or population and therefore the Indication for Use is the same as the Intended Use.

Brånemark System®:

- Healing caps are premanufactured prosthetic components to be directly connected to the endosseous dental implants or abutments and are indicated as temporary components for single tooth to full arch denture procedures.
- Dental implant abutments in combination with two-stage endosseous implants are used as the foundation for anchoring tooth replacement in either jaw. Restorations range from replacing one single tooth to fixed partial and full dentures using cement-retained or screw-retained supra-constructions.
- The Plastic Caps with O-ring are premanufactured prosthetic components to be directly connected to the endosseous dental implants or abutments and are indicated as temporary components for partial or full arch denture procedures.

Steri-Oss™ and Replace™ External Hex:

- Temporary copings in combination with two-stage endosseous implants are used as the foundation for anchoring tooth replacement in either jaw. Restorations range from replacing one single tooth to fixed partial and full dentures using cement-retained or screw-retained supra-constructions.
- Dental implant abutments in combination with two-stage endosseous implants are used as the foundation for anchoring tooth replacement in either jaw. Restorations range from replacing one single tooth to fixed partial and full dentures using cement-retained or screw-retained supra-constructions.

Immediate Provisional Implant (IPI):

- The caps are premanufactured prosthetic components to be directly connected to the endosseous dental implants or abutments and are indicated as temporary components for multiple teeth to full arch denture procedures.
- The copings are premanufactured prosthetic components to be directly connected to the endosseous dental implants or abutments and are indicated as temporary components for multiple teeth to full arch denture procedures.

Contraindications:

It is contraindicated placing the restorative components in:

- Patients who are medically unfit for an oral surgical procedure.
- Patients in whom adequate sizes, numbers or desirable positions of implants are not reachable to achieve safe support of functional or eventually parafunctional loads.
- Patients who are allergic or hypersensitive to titanium alloy Ti-6Al-4V (titanium, aluminum, vanadium).

It is contraindicated placing impression copings in:

- Patients who are allergic or hypersensitive to titanium alloy Ti-6Al-4V (titanium, aluminum, vanadium), Polyoxymethylene (POM), Polyetheretherketone (PEEK), Polybutyleneterephtalate (PBT), Stainless steel, Acetal plastic, Polyethylene terephtalate white (PET) or Gold alloy.

For laboratory components:

- None identified.

Cautions:

General:

Close cooperation between surgeon, restorative dentist and dental laboratory technician is essential for successful implant treatment.

It is strongly recommended that Nobel Biocare surgical instruments and prosthetic components are used only with Nobel Biocare implants, as combining components that are not dimensioned for correct mating can lead to mechanical and/or instrumental failure, damage to tissue or unsatisfactory esthetic results.

It is strongly recommended that clinicians, new as well as experienced implant users, always go through special training before undertaking a new treatment method. Nobel Biocare offers a wide range of courses for various levels of knowledge and experience. For more info please visit www.nobelbiocare.com.

When using a new device/treatment for the first time, working with a colleague who is experienced with the new device/treatment may help avoid possible complications. Nobel Biocare has a global network of mentors available for this purpose.

Before Surgery:

All instruments and tooling used in surgery must be maintained in good condition and care must be taken that instrumentation does not damage implants or other components.

At Surgery:

Because of the small size of the devices, care must be taken that they are not swallowed or aspirated by the patient.

Do not use temporary cement when cementing ceramic crowns due to increased risk of micro fractures.

After Surgery:

To secure the long-term treatment outcome, it is advised to provide comprehensive regular patient follow up after implant treatment and to inform about appropriate oral hygiene.

Handling Instructions:

NobelPerfect System:

Impression Coping and Implant Replica:

1. Insert the impression coping into the implant. Ensure that the connection is clean and free of any tissues. Use the Unigrip™ screwdriver and hand tighten the screw.
2. Take the radiograph to verify proper seating of the impression coping.
3. Block out the Unigrip™ screwdriver indentation on the impression coping.
4. Inject heavy body impression material (polyether material or polyvinylsiloxane) around the impression coping and into the tray. Record the impression.
5. Remove the block-out material from the Unigrip™ screwdriver indentation on the impression coping. Remove the impression coping.
6. Attach the impression coping onto the corresponding implant replica and reseat the assembly into the impression.
7. Send the impression to the dental laboratory.

Abutment:

Laboratory Procedure:

1. Produce a working model with removable gingival material.
2. Connect the abutment to the implant replica and check for occlusal clearance.
3. Modify the abutment if necessary. Do not modify the abutment connection.
4. Fabricate the crown with NobelProcera® technique or with conventional casting technique, the implant replica can be used to protect the abutment interface.

Clinical Procedure:

5. Remove temporary restoration if applicable.
6. Ensure the interface is clear from any foreign bodies before attaching the restoration.
7. Clean and disinfect the abutment prior to inserting it in the patient's mouth.
8. Tighten the abutment to 35 Ncm using the Unigrip™ screwdriver and Manual Torque Wrench Prosthetic.
9. Cement the final crown using conventional procedures after sealing of access hole. Ensure there is no excess cement. Take x-ray to verify the correct seating.

If a replacement screw is needed for NobelPerfect® restoration, a corresponding NobelReplace® screw should be ordered (for NP: article no.36818, for RP and WP: article no.29475).

Caution: Do not use temporary cement when cementing ceramic crowns due to increased risk of micro fractures.

Healing Abutment:

1. Select appropriate healing abutment and check occlusal clearance.
2. If required, clean the interface before placing the healing abutment. Connect and tighten it using Unigrip™ Screwdriver. It is recommended to verify the final abutment seating using radiographic imaging.

Brånemark System® Novum:

Laboratory procedure:

1. Attach the Novum Fixture Replicas to the respective impression copings.
2. Fabricate a gypsum model with removable soft tissue.
3. Follow the shipping instructions for NobelProcera® Scan and Design service.

Brånemark System®:

Healing cap:

Clinical procedure:

1. Select appropriate healing cap and check occlusal clearance.
2. Connect to implant and tighten using Unigrip™ Screwdriver.

Abutment Angulated:

1. Select appropriate Abutment and check occlusal clearance.
2. Connect to implant and tighten.

Abutment Complete EsthetiCone:

1. Select appropriate abutment and check occlusal clearance.
2. Connect to the implant and tighten the screw using the Screwdriver Multi-unit.

Plastic Cap with O-ring:

1. Connect the cap on the ball attachment.
2. Apply a small amount of light cure acrylic around each plastic cap and seat the denture over the caps.
3. Disengage the denture from the abutments, fill the voids with the light cure acrylic material and cure.
4. Finalize the denture.

Steri-Oss™ and Replace™ External Hex: PME temporary coping:

Clinical procedure:

1. Connect the PME temporary coping to the PME abutment and check for occlusal clearance.
2. If required, modify the coping height extraorally.
3. Fabricate a bridge using conventional technique.

Direct Abutment:

Laboratory procedure:

1. Create a master model.
2. Connect the abutment to the implant replica in the master model and check for occlusal clearance.
3. Fabricate a crown using conventional technique.

Immediate Provisional Implant (IPI): Immediate Provisional Implant Coping:

Place the copings onto the Immediate Provisional Implants:

1. Place autopolymerizing, tooth-colored acrylic into the processed acrylic shell and place over the copings.
2. After acrylic has hardened, remove the prosthesis with the copings secured in it.
3. Finalize the prosthesis and refine the occlusion.
4. Cement the restoration using temporary cement.

Immediate Provisional Implant Comfort Cap:

1. Snap the Immediate Provisional Implant Comfort Cap onto the Implant.

Materials:

NobelPerfect® System:

- Impression copings: Titanium alloy 90% Ti, 6% Al, 4% V.
- Implant replicas: Titanium alloy 90% Ti, 6% Al, 4% V.
- Abutments/healing abutments: Titanium alloy 90% Ti, 6% Al, 4% V.

Brånemark System® Novum:

- Implant replicas: Titanium alloy 90% Ti, 6% Al, 4% V.

Brånemark System®:

- Healing caps: Polybutyleneterephtalate (PBT) Pocan.
- Abutments Angulated: Unalloyed Titanium Grade 1 and 4; Screw: Titanium alloy 90% Ti, 6% Al, 4% V.
- Abutments Complete/EsthetiCone: Unalloyed Titanium Grade 1 and 4; Screw: Titanium alloy 90% Ti, 6% Al, 4% V.
- Ball attachment housings (Plastic Caps with O-ring): Rubber; O-ring: Buna-N-Nitril, Plastic cap: Polyetheretherketone (PEEK).

Steri-Oss™ and Replace™ External Hex:

- Temporary coping & screw: Titanium alloy 90% Ti, 6% Al, 4% V.
- Direct Abutment Plastic: Acetal (Delrin) Plastic; screw: Titanium alloy 90% Ti, 6% Al, 4% V.
- Direct Abutment Gold/Plastic: Acetal (Delrin) Plastic; screw: Titanium alloy 90% Ti, 6% Al, 4% V.
- Coping Gold/Plastic: Gold Alloy for Copings, Acetal (Delrin) Plastic, screw: Titanium alloy 90% Ti, 6% Al, 4% V.
- PME Coping Gold/Plastic: Gold Alloy for Copings, screw: Titanium alloy 90% Ti, 6% Al, 4% V.

Immediate Provisional Implant (IPI):

- Copings: Titanium alloy 90% Ti, 6% Al, 4% V.
- Caps: Polyethylene terephtalate white (PET).

Sterility and Reusability Information:

NobelPerfect® System:

NobelPerfect® Impression Coping:

The NobelPerfect® Impression Coping is delivered non-sterile and intended for reuse. Prior to reuse clean, disinfect and sterilize the product using the recommended parameters.

Warning: Do not use the device if the packaging has been damaged or previously opened.

Warning: Use of non-sterile device may lead to infection of tissues or infectious diseases.

NobelPerfect® Implant Replica:

The NobelPerfect® Implant Replica is delivered non-sterile and intended for reuse.

Note: The Implant Replica is used only in the dental laboratory (no intraoral use) and has no cleaning and sterilization requirements.

NobelPerfect® Abutment:

The NobelPerfect® Abutment is delivered non-sterile for single use only. Prior to use clean, disinfect and sterilize the product using the recommended parameters.

Warning: Do not use the device if the packaging has been damaged or previously opened.

Warning: Use of non-sterile device may lead to infection of tissues or infectious diseases.

Caution: The NobelPerfect® Abutment is a single use product that must not be reprocessed. Reprocessing could cause loss of mechanical, chemical and/or biological characteristics. Reuse could cause infection.

NobelPerfect® Healing Abutment:

The NobelPerfect® Healing Abutment is delivered sterile for single use only. Do not use after the labeled expiration date.

Warning: Do not use device if the packaging has been damaged or previously opened.

Caution: The NobelPerfect® Healing Abutment is a single use product that must not be reprocessed. Reprocessing could cause loss of mechanical, chemical and/or biological characteristics. Reuse could cause infection.

Warning: Do not use device if the packaging has been damaged or previously opened.

Brånemark System® Novum:

Replica Fixture Novum:

The Replica Fixture Novum is delivered non-sterile and intended for reuse. Note: implant replica is used only in the dental laboratory (no intraoral use) and has no cleaning and sterilization requirements.

Brånemark System®:

Nobel Biocare Replacement Parts
Instructions for Use

Nobel Biocare™

Healing caps and Plastic Caps with O-ring:

The Healing caps and Plastic Caps with O-ring are delivered non-sterile for single use only. Prior to use clean, disinfect and sterilize the product using the recommended parameters.

Warning: Use of non-sterile device may lead to infection of tissues or infectious diseases.

Warning: Do not use the device if the packaging has been damaged or previously opened.

Caution: The Healing caps and Plastic Caps with O-ring are single use products that must not be reprocessed. Reprocessing could cause loss of mechanical, chemical and/or biological characteristics. Reuse could cause infection.

Angulated Abutments and Complete/ EsthetiCone Abutments:

The Angulated Abutments and Complete/ EsthetiCone Abutments are delivered sterile for single use only.

Warning: Do not use if the packaging has been damaged or previously opened.

Warning: Use of non-sterile components may lead to infection of tissues or infectious diseases.

Caution: The Angulated Abutments and Complete/ EsthetiCone Abutments are single use products that must not be reprocessed. Reprocessing could cause loss of mechanical, chemical and/or biological characteristics. Reuse could cause infection.

Steri-Oss™ and Replace™ External Hex:

The PME temporary copings, PME Gold Copings, Direct Abutments, and Gold Copings are delivered non-sterile for single use only. Prior to use clean, disinfect and sterilize the product using the recommended parameters.

Warning: Use of non-sterile device may lead to infection of tissues or infectious diseases.

Warning: Do not use the device if the packaging has been damaged or previously opened.

Caution: The PME temporary copings, PME Gold Copings, Direct Abutments, and Gold Copings are single use products that must not be reprocessed. Reprocessing could cause loss of mechanical, chemical and/or biological characteristics. Reuse could cause infection.

Immediate Provisional Implant (IPI):

The IPI Coping and IPI Comfort Cap are delivered non-sterile for single use only. Prior to use clean, disinfect and sterilize the product using the recommended parameters.

Warning: Use of non-sterile device may lead to infection of tissues or infectious diseases.

Warning: Do not use the device if the packaging has been damaged or previously opened.

Caution: The IPI Coping and IPI Comfort Cap are single use products that must not be reprocessed. Reprocessing could cause loss of mechanical, chemical and/or biological characteristics. Reuse could cause infection.

Cleaning and Sterilization Instructions:

Cleaning and sterilization instructions for devices which are delivered non-sterile by Nobel Biocare, are intended for single user or reuse, and must be sterilized by the user prior to each use, where the devices are individually sealed in pouches during sterilization.

With these cleaning and sterilization instructions, Nobel Biocare provides a validated procedure to ensure clean and sterile products. According to EN ISO 17664, it remains the responsibility of the processor to ensure that the reprocessing as actually performed using equipment, materials and personnel in the reprocessing facility achieves the desired result. Likewise, any deviation by the processor from the provided instructions should be properly evaluated for effectiveness and potential adverse consequences.

Cleaning Guidelines:

Clean the device using automated or manual cleaning, disinfect and dry the device.

Automated Cleaning, Disinfection and Drying (Including Pre-cleaning):

The following washer/disinfector was used in the Nobel Biocare validation: Miele G7836 CD.

Note: The manufacturer's instructions for use for any detergent / cleaning solution and/or equipment and accessories used to clean, disinfect, and/or dry the device(s) must be strictly followed where applicable.

1. Disassemble the devices, where applicable.
2. Immerse in cold enzymatic cleaning agent 0.5% (e.g. Neodisher Medizym) for 5 minutes.
3. Fill lumina (where applicable) with cleaning solution 0.5% (e.g. Neodisher Medizym) with a syringe.
4. Brush the outer surfaces with a soft bristled nylon brush (e.g. Medsafe MED-100.33) until all visible residues are removed.
5. Brush the inner surfaces, lumina and cavities (where applicable) with bottle brushes (e.g. OD = 1.2mm / 2.0mm / 5.0mm) until all visible residues are removed.
6. Rinse with cold running tap water.
7. Rinse lumina (where applicable) with a syringe with 20ml tap water.
8. Load devices into washer / disinfector.
9. Perform automatic cleaning and disinfection under consideration of national requirements with regard to the A0-Value (EN ISO 15883). The following parameters are based on the Vario TD program on the Miele G7836 CD Washer-disinfector:

- 2 min pre-cleaning with cold water
- Draining
- 5 minutes cleaning with 55°C tap water and 0.5% alkaline cleaning agent (e.g. Neodisher Mediclean)
- Draining
- 3 minutes neutralization with cold desalinated water
- Draining
- 2 minutes rinsing with cold desalinated water
- Draining

10. Run drying cycle.
11. Dry with compressed air or wipes if needed.

Manual Cleaning, Disinfection and Drying:

Note: The manufacturer's instructions for use for any detergent / cleaning solution and/or equipment and accessories used to clean, disinfect, and/or dry the device(s) must be strictly followed where applicable.

1. Disassemble the device(s), where applicable.
2. Immerse devices for a minimum of 5 minutes in sterile NaCl solution.
3. Scrub the outer side of the devices with soft bristled nylon brush until all visible soil is removed.
4. Flush channels / lumina (where applicable) with 20ml cleaning solution (e.g. Cidezyme ASP) with an irrigation needle connected to a 20ml syringe.
5. Brush lumina (where applicable) with a bottle brush (e.g. OD = 1.2mm / 2.0mm / 5.0mm).
6. Rinse the outer side and lumina of the devices with cold running tap water to remove all cleaning solutions.
7. Immerse in ultrasonic bath with 0.5% enzymatic Detergent Solution (e.g. Cidezyme ASP) and treat for 5 min at 40°C (104°F).
8. Flush inner lumina (where applicable) with 20ml cold running tap water with an irrigation needle connected to a 20ml syringe.
9. Rinse the outer side of the devices with purified or sterile water to remove all cleaning solutions.
10. Repeat cleaning steps if needed.
11. Immerse in 100% disinfection solution (e.g. Cidex OPA) for 5 minutes.
12. Flush internal channels / lumina (where applicable) with disinfection solution.
13. Rinse and flush lumina and outer side of devices with cold running tap water.
14. Flush internal channels / lumina (where applicable) with purified or sterile water.
15. Dry with compressed air or wipes.
16. Repeat complete cleaning and disinfection if needed.

Visual Inspection:

After cleaning, disinfection, and drying, inspect the device for unacceptable deterioration such as corrosion, discoloration, pitting, cracked seals and properly dispose any devices that fail the inspection.

Sterilization:

Assemble (where applicable), inspect and seal the single device in a suitable sterilization pouch and steam sterilize. Both the gravity cycle (saturated steam) and pre-vacuum (forced air removal) cycle can be applied, using the following parameters:

Sterilization Parameters for GB Master IFU:

- Gravity Cycle Method: Steam sterilization at 132°C (270°F) for 10 minutes, followed by drying for a minimum of 10 minutes in chamber.
- Pre-Vacuum Method: Steam sterilization at 132°C (270°F) for 3 minutes, followed by drying for a minimum of 10 minutes in chamber.
- Pre-Vacuum Method (for UK): Steam sterilization at 134°C (273°F) for 3 minutes, followed by drying for a minimum of 10 minutes in chamber.
- Pre-Vacuum Method (recommended to ensure inactivation of prions): Steam sterilization at 134°C (273°F) for 18 minutes, followed by drying for a minimum of 20 minutes in chamber.

Magnetic Resonance (MR) Safety Information:

These articles have not been evaluated for safety and compatibility in the MR environment. They have not been tested for heating, migration, or image artifact in the MR environment. The safety in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

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.

Nobel Biocare Replacement Parts
Instructions for Use

Manufacturer and Distributor:

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

Distributed in Australia by:
Nobel Biocare Australia Pty Ltd
Level 4/7 Eden Park Drive
Macquarie Park, NSW 2114 Australia
Phone: +61 1800 804 597

Distributed in New Zealand by:
Nobel Biocare New Zealand Ltd
33 Spartan Road
Takanini, Auckland, 2105 New Zealand
Phone: +64 0800 441 657

CE 0086 — CE Mark for Class II Devices

CE — CE Mark for Class I Devices

Canada – License Exemption: Please note that not all products may have been licensed in accordance with Canadian law.

Symbols Glossary:

The following table describes symbols which may be present on the device labeling. Refer to the device labeling for the symbols which are applicable to the device.

LOT — Batch code	REF — Catalogue number	Caution	Consult instructions for use
PHT DEHP — Contains or presence of phthalate	Date of manufacture	2 STERILIZE — Do not re-sterilize	2 — Do not reuse
Do not use if package is damaged	Rx Only — For prescription use only	ID — Patient Identifier	Keep away from sunlight
Keep dry	symbol.glossary.nobelbiocare.com ifu.nobelbiocare.com — Link to Online Symbols Glossary and IFU Portal	Manufacturer	
MD — Medical device	MR — Magnetic resonance conditional	NON STERILE — Non-sterile	# — Patient number
SN — Serial number	STERILE R — Sterilized using irradiation	Use-by date	