

# Notice of Instructions



This notice applies to the following **euroteknika** implants



See overleaf for **euroteknika** references covered by this notice.

## Introduction

The **euroteknika** dental implant must only be used by trained professionals with implant expertise and who have read this notice and the product user's guide.

## Warning

The practitioner is responsible for designing the prosthesis that will be used with the **euroteknika** dental implant (number, size and location). The practitioner must assess whether the patient is a suitable candidate for implants (See Contraindications.). The practitioner is responsible for the required preoperative examinations (verify bone density and quality), as well as for medications prescribed as part of the procedure. Strict sterile conditions must be maintained throughout surgery.

The prosthesis required for a **euroteknika** dental implant must be designed by a qualified professional so as to be perfectly balanced. Uneven load distribution can cause the final prosthesis to break and/or the implant to fracture or be rejected, even if it has been already successfully integrated.

**euroteknika**'s User Guide contains answers to the most frequently asked questions. In case of doubt, refer to the abundant literature available on implantology.

**euroteknika** dental implants should be placed using only the instruments recommended by **euroteknika** for the selected product. The prosthesis must be only built with components from the **euroteknika** line corresponding to the selected implant.

Surgical instruments and prosthetic components must be autoclaved (minimum of 18 minutes at 134°C) before the procedure. The sterilization process must be validated by the practitioner in accordance with a method recognized by the authorities of the product country of use. We refer the practitioner to the notice of instructions of the autoclave manufacturer for the use of the autoclave. In case another sterilization method is used, it is up to the practitioner to check that it is recognized by the authorities of the product country of use.

**euroteknika** dental implants are designed for single use. Never reuse an extracted and/or rejected implant. The reuse of an implant and/or prosthetic component can lead to infections.

## Indications for use

**euroteknika** dental implants are intended for surgical placement in the upper or lower jaw to replace a root. They provide a mean for a permanent or removable prosthetic attachment and can be used to treat most other clinical cases (partial or full edentulous spans).

**euroteknika** dental implants are manufactured from titanium or titanium alloy in accordance with ISO standards 5832-2 and 5832-3.

## Contraindications

Assess patients carefully to determine whether they are suitable candidates for implants. The main contraindications are infectious diseases, blood disorders and/or clotting problems, immune deficiency, radiation of the face, poor bone quality, localized bone tumor, chronic bruxism, smoking, alcoholism, drug addiction, poor oral hygiene, and patient ability to understand and follow instructions. Consult implantology textbooks, relevant medical works and products user's guides for further contraindications.

## Side effects and adverse reactions

Inform patients of potential adverse reactions associated with the use of dental implants (bone fracture, infection, pain, hematoma, oedema, temporary or permanent nerve damage, hemorrhage, etc.). Patient's informed consent must be obtained before surgery.

## Handling and storage

**euroteknika** dental implants are supplied sterile. Handle packaging carefully so as to ensure the device remains sterile. Store devices in a dry, well-ventilated location (never expose to direct sunlight or store near a source of heat). Use before the expiration date printed on the label. Do not use the product if the packaging has been damaged or previously opened.

## Preparation of the surgical site

Make sure all instruments are in excellent condition before beginning the procedure. Only sharp instruments of the highest quality should be used for any surgical procedure involving bone. Under no circumstances exceed the prescribed number of uses (use the cursors provided in the surgical kit - see User Guide). If in doubt as to the instrument's sharpness, use a new one.

Utilize continuous irrigation with a cool, sterile irrigating solution to avoid excessive damage to the surrounding tissue and to prevent compromised osteo-integration by heating the bone.

## Implant placement

Make sure the implant does not come into contact with contaminants once it is removed from its packaging.

## Elimination of waste and consumables

The single-use soiled items are considered bio-hazardous waste and as such must be collected and disposed of in accordance with the relevant legislation.

## Implant removal

If necessary, consult the User Guide on the procedure for implant removal.

## Traceability

Ensure implant traceability by keeping the label in the patient's file.

Products Covered by This Notice - Catalog Numbers

UNIVERSAL+ Line (EC Marking 1997 for Universal line)							
Ø Implant	Height 5 mm	Height 7 mm	Height 8,5 mm	Height 10 mm	Height 11,5 mm	Height 13 mm	Height 15 mm
Ø 3,75 mm		UID 37.41.070	UID 37.41.085	UID 37.41.100	UID 37.41.115	UID 37.41.130	UID 37.41.150
Ø 4 mm		UID 40.41.070	UID 40.41.085	UID 40.41.100	UID 40.41.115	UID 40.41.130	UID 40.41.150
Ø 4,75 mm	UID 47.49.050	UID 47.49.070	UID 47.49.085	UID 47.49.100	UID 47.49.115	UID 47.49.130	UID 47.49.150
Ø 6 mm	UID 60.62.050	UID 60.62.070	UID 60.62.085	UID 60.62.100	UID 60.62.115	UID 60.62.130	

UNEVA (EC Marking 2008)					
Ø Implant	Height 6 mm	Height 8 mm	Height 10 mm	Height 12 mm	Height 14 mm
Ø 3,6 mm		UED 36.41.080	UED 36.41.100	UED 36.41.120	UED 36.41.140
Ø 4,1 mm		UED 41.41.080	UED 41.41.100	UED 41.41.120	UED 41.41.140
Ø 4,8 mm	UED 48.49.60	UED 48.49.080	UED 48.49.100	UED 48.49.120	UED 48.49.140
Ø 6 mm	UED 60.62.060	UED 60.62.080	UED 60.62.100	UED 60.62.120	

UNEVA for guided surgery (EC Marking 2008)					
Ø Implant	Height 6 mm	Height 8 mm	Height 10 mm	Height 12 mm	Height 14 mm
Ø 3,6 mm		UED 36.41.080	UED 36.41.100	UED 36.41.120	UED 36.41.140
Ø 4,1 mm		UED 41.41.080	UED 41.41.100	UED 41.41.120	UED 41.41.140
Ø 4,8 mm	UED 48.49.60	UED 48.49.080	UED 48.49.100	UED 48.49.120	UED 48.49.140

AESTHETICA Line (EC Marking 2005)						
Ø Implant	Ø neck	Height 6 mm	Height 8 mm	Height 10 mm	Height 12 mm	Height 14 mm
3.6 mm	4.2 mm		AID 36.42.080	AID 36.42.100	AID 36.42.120	AID 36.42.140
3.6 mm	4.8 mm		AID 36.48.080	AID 36.48.100	AID 36.48.120	AID 36.48.140
4.1 mm	4.2 mm	AID 41.42.060	AID 41.42.080	AID 41.42.100	AID 41.42.120	AID 41.42.140
4.1 mm	4.8 mm	AID 41.48.060	AID 41.48.080	AID 41.48.100	AID 41.48.120	AID 41.48.140
4.8 mm	4.8 mm	AID 48.48.060	AID 48.48.080	AID 48.48.100	AID 48.48.120	AID 48.48.140
4.8 mm	6.5 mm	AID 41.65.060	AID 41.65.080	AID 41.65.100	AID 41.65.120	AID 41.65.140












AESTHETICA+ Line (EC Marking 2009)						
Ø Implant	Ø neck	Height 6 mm	Height 8 mm	Height 10 mm	Height 12 mm	Height 14 mm
3.6 mm	4.2 mm		AIE 36.42.080	AIE 36.42.100	AIE 36.42.120	AIE 36.42.140
3.6 mm	4.8 mm		AIE 36.48.080	AIE 36.48.100	AIE 36.48.120	AIE 36.48.140
4.1 mm	4.2 mm	AIE 41.42.060	AIE 41.42.080	AIE 41.42.100	AIE 41.42.120	AIE 41.42.140
4.1 mm	4.8 mm	AIE 41.48.060	AIE 41.48.080	AIE 41.48.100	AIE 41.48.120	AIE 41.48.140
4.8 mm	4.8 mm	AIE 48.48.060	AIE 48.48.080	AIE 48.48.100	AIE 48.48.120	AIE 48.48.140
4.8 mm	6.5 mm	AIE 41.65.060	AIE 41.65.080	AIE 41.65.100	AIE 41.65.120	AIE 41.65.140

NATURALL Line (EC Marking 2007)					
Type of Connection	Ø Implant	Height 8 mm	Height 10 mm	Height 12 mm	Height 14 mm
External	Ø 3 mm	NIC 30 080	NIC 30 100	NIC 30 120	NIC 30 140
Internal	Ø 3.5 mm	NIC 35 080	NIC 35 100	NIC 35 120	NIC 35 140
Internal	Ø 4 mm	NIC 40 080	NIC 40 100	NIC 40 120	NIC 40 140
Internal	Ø 4.5 mm	NIC 45 080	NIC 45 100	NIC 45 120	NIC 45 140
Internal	Ø 5 mm	NIC 50 080	NIC 50 100	NIC 50 120	NIC 50 140

NATEA Line (EC Marking 2008)					
Ø Implant	Height 6 mm	Height 8 mm	Height 10 mm	Height 12 mm	Height 14 mm
Ø 3.6 mm		NID 36 37 080	NID 36 37 100	NID 36 37 120	NID 36 37 140
Ø 4.1 mm		NID 41 42 080	NID 41 42 100	NID 41 42 120	NID 41 42 140
Ø 4.8 mm	NID 48 49 060	NID 48 49 080	NID 48 49 100	NID 48 49 120	NID 48 49 140
Ø 6 mm	NID 60 62 060	NID 60 62 080	NID 60 62 100	NID 60 62 120	NID 60 62 140

OBI Line (EC Marking 2005)				
Lines	Height 9 mm	Height 11 mm	Height 13 mm	Height 15 mm
Mini implant OBI	OIC 27.68.090	OIC 27.68.110	OIC 27.68.130	OIC 27.68.150
Implant OBI Abutment	OIC 27.85.090	OIC 27.85.110	OIC 27.85.130	OIC 27.85.150

NF EN 980 Symbol – 07/2008

Do not re-use 	Use by date 	Date of manufacture 	Sterilized using gamma irradiation 
Caution, consult Notice of Instructions 	Manufacturer 	Consult Instructions for Use 	Do not use if package is damaged 
Keep away from light 	Keep dry 	Do not re-sterilize 	

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Our implants range have the CE marking, in conformity with the European directive n°93/42/CEE - N° CE 0499 - Notice\_A\_ETK-GB-0110-V1-4