Usage Instructions

BONE DRILLING INSTRUMENTS
The techniques employed in the realization of surgery with these Bone Drilling instruments are highly specialized and involve specific procedures that must be performed by a professional specialized in this area. Inadequate choices of surgical Bone Drilling instruments, as well as use without knowledge of correct procedures or under inadequate conditions may cause unwanted results. The Bone Drilling Instruments are reusable products with a specific shape and size for each implant, and installation sequence must be observed.

**USAGE INDICATIONS** ........................................................

Lance Drill 2.0: A surgical instrument used to breach the cortical and, if preferred, to realize the first perforation of the bone bed.

Cylindrical Drill: A surgical instrument used to prepare the surgical cavity for Inttegra System implants.

Conical Drill: A surgical instrument used to prepare the surgical cavity for Duo System implants.

Countersink Drill: A surgical instrument used to prepare the bone crest to receive the cervical third of Signo Vinces® Inttegra System implants.

Pilot Drill: Intermediary function in the surgical cavity done by Inttegra System Helical Drills. Increases the cavity of the previous drill, to guide and facilitate the entry of the next drill, according to the surgical...
sequence of the Inttegra System’s implant.

Trefina-Drill: A surgical instrument used for cases where there is the need to collect bone tissue or to remove implants.

FORMS OF PRESENTATION

Lance Drill 2.0: Manufactured in surgical steel, non-sterile and conditioned in envelope with film and surgical grade paper and a secondary cardboard packaging.
Diameter: 2.0mm
Length: 35mm
Depth Engraving: 8.5, 10, 11.5, 13 and 15mm.

Cylindrical Drill: Manufactured in surgical steel, non-sterile and conditioned in envelope with film and surgical grade paper and a secondary cardboard packaging.
Diameter: 2.6, 3.0, 3.15, 3.3, 3.8 and 4.3mm
Length: 35mm
Depth Engraving: 8.5, 10, 11.5, 13 and 15mm.

Conical Drill: Manufactured in surgical steel, non-sterile and conditioned in envelope with film and surgical grade paper and a secondary cardboard packaging.
Diameter: 3.8, 4.6 and 5.5mm
Length: 31 and 34mm
Depth Engraving: 8.5 and 10mm (Length 31mm) and 11.5, 13 and 15 (length 34mm)
Countersink Drill: Manufactured in surgical steel, non-sterile and conditioned in envelope with film and surgical grade paper and a secondary cardboard packaging.
Diameters: 3.3/2.6 (Implant 3.25), 4.1/3.0 (Implant 3.75), 4.1/3.3 (Implant 4.0) and 5.0/4.3 (Implant 5.0)
Length: 35mm
Pilot Drill: Manufactured in surgical steel, non-sterile and conditioned in envelope with film and surgical grade paper and a secondary cardboard packaging.
Diameters: 2.6/3.3mm, 3.0/3.8mm
Length: 35mm
Trefina Drill: Manufactured in surgical steel, non-sterile and conditioned in envelope with film and surgical grade paper and a secondary cardboard packaging.
Diameters: 3.3mm, 4.1mm and 5mm
Length: 32mm

HANDLING ..............................................................................
The Bone Drilling Instruments Signo Vinces® are used to prepare the recipient bed and be done with care to reduce the surgical trauma. The Bone Drilling Instruments Signo Vinces® are connected to a counter-angle powered by an engine to implant. Select the drill sequence in accordance with the
implant to be installed. Insertion depths (laser engraving) should be respected in accordance with implant length as well as prosthetic platform. Use:
1. Drills in good cutting condition
2. Cutting speeds as indicated in the table:
   Instrument Speed (rpm)
   Lance Drill ................. 800 a 1000
   Cylindrical Drill .......... 500 a 1000
   Conical Drill ............... 500 a 1000
   Pilot Drill .................. 500 a 1000
   Countersink Drill .......... 300 a 500
   Trefina Drill-Boher ...... 150 a 300
3. Abundant irrigation

**SANITIZATION**

Signo Vinces® Bone Drilling Instruments must be correctly sanitized after each use.

. Use enzymatic detergent (10% solution), immersing instruments completely;
. In ultra-sonic washer, leave approximately 10 minutes;
. Distilled water should be used abundantly to rinse, observing the complete lack of residue. Brushing is allowed during sanitization;
. Dry with clean cloth or compressed air;
. In case the sanitization procedure is not successful, repeat until satisfactory results are achieved;
. Select the packaging according to the sterilization
process, preferably film envelopes and surgical grade paper. Warning: Stocking the material without completely drying will cause oxidation. The use of scale solvents tends to darken the instruments and also provoke oxidation. The enzymatic liquid in a concentration superior to 10% also favors oxidation.

**STERILIZATION**

Signo Vinces® Bone Drilling Instruments are reusable and are supplied non-sterile. They must be sterilized before usage. Caution: do not sterilize the Bone Drilling Instruments in the plastic bags (blister). Sterilize on the day before or on the day of the procedure. Vapor sterilization is the preferred and recommended sterilization method, as well as the parameters and procedures established in the BS EN ISO 17665-1:2006 Sterilization of health care products norm. Moist heat. Requirements for the development, validation and routine control for a sterilization process for medical devices; or follow procedures documented in the sterilizer manual. The sterilization is valid from 7 to 15 days, as long as kept in a clean environment, dry and away from sunlight.
COUNTER-INDICATIONS ..............................................
Signo Vinces® Bone Drilling Instruments do not present counter-indications as long as their intended use is followed correctly.

WARNING ...........................................................................
The original condition of the product will only be maintained as long as the packaging is not violated. The Bone Drilling Instruments Signo Vinces® are not sharpening again. Make sure that the drills are in good cutting, and use plenty of cooling with sterile saline in order to maintain the temperature of the bone as low as possible, preventing overheating commit to healing and ultimately bone-integration of implant.

STOCKING ..........................................................................
Signo Vinces® Bone Drilling Instruments should be kept in a dry location, away from sunlight and at room temperature.

DISPOSAL OF MATERIALS .............................................
All consumable materials used in the installation process may present health risks to the handler. Before disposal of these materials, consulting and following standing regulations is recommended.
LIFESPAN
Signo Vinces® Bone Drilling Instruments must be disposed of upon loss of their functionality.

VALIDITY
All Signo Vinces® Bone Drilling Instruments have a 5-year validity period.

TRANSPORTATION
The packaging protects against falls and collisions. In case of large distances, additional packaging is advised.
SYMBOLS NORM ACCORDING
EN ISO 15223:2012

Authorized dealer
Manufacturer Batch code
Manufacturing date Manufacturer
Consult instructions for use Batch code
Reference number Consult instructions for use
Use by
Don’t use if the packing is damaged Unsterile product
Keep away from sunlight
Keep dry
Attention, consult accompanying documents
SIGNO VINCES EQUIPAMENTOS ODONTOLÓGICOS LTDA.
Av. Padre Natal Pigatto, 1095
83607-240 Campo Largo - PR
Tel. 55 41 3032-5999
Fax 55 41 3392-3594
CNPJ: 03.717.757/0001-99
IE: 902.12465-97
signovincs@signovinces.com.br
www.signovinces.com.br

Technical Responsibility:
Eng. Andreas R. Firzlaff CREA 29.522/D-PR
Registration n° ANVISA.: 80389000008

Signo Vinces Europa Lda.
Av. 5 de outubro, 151 7ºA
1050.053 - Lisbon - Portugal

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