



	TECHNICAL DATA SHEET	CODE: TDS_008
	INSTRUMENTAL	DATE: 26/Ago/16
	BESTDENT	VERSION: 01

<b>PRODUCTO</b>	INSTRUMENTAL BESTDENT	
<b>REFERENCIA</b>	Ver anexo	
<b>FABRICANTE / RESPONSABLE</b>	CORIS ARMITAL SL PLAZA XAROL, NUM 26-28 POL. IND. LES GUIXERES 08915 BADALONA, SPAIN	
<b>CLASIFICACIÓN DEL PRODUCTO</b>	Producto Sanitario clase I, Directiva 93/42/CEE	
<b>DESCRIPCIÓN DEL PRODUCTO</b>	Instrumentos para la práctica odontológica	
<b>ESPECIFICACIONES</b>	Descripción del material: Acero inoxidable. Acabado: superficie lisa y libre de grietas. Dureza HRC (Rockwell): max 40-44 Tipo de material: AISI 410	
<b>EMBALAJE</b>	Cada instrumento está envasado en una bolsa de polietileno de alta densidad con ambos extremos sellados.	
<b>CADUCIDAD</b>	N.A. Las propiedades, la función o uso no se ven afectadas de forma automática si se almacena correctamente.	
<b>FINALIDAD</b>	Destinados a ser utilizados durante las operaciones llevadas a cabo en las clínicas dentales por el personal cualificado.	
<b>INFORMACIÓN SOBRE LA SEGURIDAD</b>	Los dispositivos son reutilizables, sin embargo es necesaria la limpieza y esterilización antes de cada uso. Si existe algún indicio de óxido, el instrumento no debe utilizarse.	
<b>CONDICIONES DE TRANSPORTE Y ALMACENAMIENTO</b>	Instrucciones de limpieza se proporcionan junto con los instrumentos.	
<b>MSDS</b>	N.A.	


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80204	PINZA PAPEL ARTICULAR - BD
80205	ESPATULA CEMENTO DOBLE -BESTDENT
80206	MANGO DE BISTURI N.3 - BD
80207	PORTA-AGUJAS MAYO 15cm. BESTDENT
80208	TIJERA CIRUGIA CURVA BESTDENT
80209	PINZA MOSQUITO RECTA 12,5 cm BESTDENT
80210	SONDAS EXPLORACION (4u.) BESTDENT
80212	CUCHILLO DE CERA BESTDENT
80213	PORTAMATRICES UNIVERSAL BESTDENT
80214	PERFORADOR DIQUES BESTDENT
80215	PORTASERVILLETAS CADENA (40cm) BESTDENT
80216	PORTAMALGAMAS DOBLE DEL-TIP BESTDENT
80217	CUBETA U-2 BESTDENT
80218	CUBETA L-2 BESTDENT
80219	CUBETA U-4 BESTDENT
80220	JERINGA ASPIRACION 1 ARO BESTDENT
80221	MECHERO DE ALCOHOL BESTDENT
80222	JERINGA ASPIRACION 3 AROS BESTDENT
80223	CUBETAS PERFORADAS Est.10u. BESTDENT
80224	PINZA CON CIERRE BESTDENT
80225	PINZA GUBIA CURVA -BESTDENT
80227	BOTADOR WINTER 14L
80228	BOTADOR WINTER 14R BESTDENT
80229	BOTADOR RECTO ANCHO BESTDENT
80230	BOTADOR RECTO MEDIO BESTDENT
80231	BOTADOR RECTO FINO BESTDENT
80232	FORCEPS N.1 BESTDENT
80233	FORCEPS N.7 BESTDENT
80234	FORCEPS N.13 BESTDENT
80237	FORCEPS N.22 BESTDENT
80238	FORCEPS N.33 BESTDENT
80239	FORCEPS N.51 BESTDENT
80240	FORCEPS N.51A BESTDENT
80241	FORCEPS N.67A BESTDENT
80242	FORCEPS N.79 BESTDENT
80243	FORCEPS N.86 C BESTDENT

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80244	PICH DOBLE BESTDENT
80245	BRUÑIDOR 27/29 BESTDENT
80246	PERIOTOTOMO BESTDENT
80247	LEVANTAPUENTES BESTDENT
80248	PORTAMALGAMAS MATE BESTDENT
80249	PORTACLAMPS BESTDENT
80251	PORTA-AGUJAS CASTROVIEJO CURVO BESTDENT
80252	SEPARADOR MINESOTA BESTDENT
80253	ARCO DE YOUNG METALICO BESTDENT
80254	PINZAS PORTAPLACAS LARGAS (6u.) - BD
80255	JERINGA AUTOASPIRANTE BESTDENT
80256	CALIBRADOR BESTDENT
80257	PINZA MATHIEU PARA LIGADURAS BESTDENT
80258	CAJA DE ACERO INOXIDABLE BESTDENT
80259	CUBETA U-1 BESTDENT
80260	CUBETA L-1 BESTDENT
80261	CUBETA L-4 BESTDENT
80262	CUBETA U-5 BESTDENT
80263	CUBETA L-5 BESTDENT
80264	CUBETAS GIRATORIAS PERFORADAS - BD
80265	CUBETAS PARCIALES DCHA+IZDA - BD
80266	CUBETA PERFORADA U-1 BESTDENT
80267	CUBETA PERFORADA L-1 BESTDENT
80268	CUBETA PERFORADA U-2 BESTDENT
80269	CUBETA PERFORADA L-2 BESTDENT
80270	CUBETA PERFORADA U-3 BESTDENT
80271	CUBETA PERFORADA L-3 BESTDENT
80272	CUBETA PERFORADA U-4 BESTDENT
80273	CUBETA PERFORADA L-4 BESTDENT
80274	CUBETA PERFORADA U-5 BESTDENT
80275	CUBETA PERFORADA L-5 BESTDENT
80276	TIJERA METALES CURVA 10 cm BESTDENT
80277	ATACADOR N.160 BESTDENT
80278	MEDIDOR IWANSON BESTDENT
80279	BOTADOR WINTER 11R BESTDENT
80280	BOTADOR WINTER 11L BESTDENT
80281	BOTADOR APICES DCHO BESTDENT
80282	BOTADOR APICES IZDO BESTDENT
80283	BOTADOR RECTO MUY FINO BESTDENT
80284	FORCEPS N.33A BESTDENT
80285	FORCEPS N.89 BESTDENT
80286	FORCEPS N.90 BESTDENT
80287	CLEOIDE-DISCOIDE BESTDENT
80288	EXCAVADOR N.17 BESTDENT
80289	EXCAVADOR N.18 BESTDENT

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80290	MARKLEY 2M BESTDENT
80291	ESPACIADOR A30 BESTDENT
80292	ESPACIADOR A40 BESTDENT
80293	ESPATULA ALGINATO TIPO ASH BESTDENT
80296	PINZA ALBRECH BESTDENT
80297	TIJERA CASTROVIEJO BESTDENT
80300	DAPPEN AMALGAMA BESTDENT
80301	SOPORTE CON 10 PINZAS PARA RX BESTDENT
80302	SEPARADORES FARABEUFF BESTDENT
80303	BOTADOR POTT DCHO. BESTDENT
80304	BOTADOR POTT IZDO. BESTDENT
80305	PINZA FINA CIRUGIA SIN DIENTE BESTDENT
80306	PINZA CIRUGIA CON DIENTE BESTDENT
80307	PINZA ADSON SIN DIENTE BESTDENT
80308	PINZA ADSON CON DIENTE BESTDENT
80309	MANGO BISTURI RECTO (REDONDO) BESTDENT
80310	ADAPTADOR BANDAS MERSHON BESTDENT
80311	PINZA POSICIONADOR BRACKETS BESTDENT
80312	PINZA SEPARADORES ELASTICOS BESTDENT
80313	ALICATE CORTAR ALAMBRE GRUESO BESTDENT
80314	ALIC CORTA ALAMB GRUESO MANGOS GOMA - BD
80315	GUIA/DIRECCIONADOR LIGADURAS CURVO BD
80316	GUIA/DIRECCIONADOR LIGADURAS RECTO - BD
80317	APLICADOR LIGADURAS ELASTICAS BESTDENT
80318	ESTRELLA ALTIMETRO PARA BRACKETS - BD
80319	ALICATE DESPEGAR BRACKETS CURVO - BD
80320	ALICATE 3 PUNTAS/PICOS ADERER BESTDENT
80321	ALICATE 3 PUNTAS/ARCOS FACIALES - BD

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	BESTDENT	Version: 02

<b>PRODUCT</b>	<b>INSTRUMENTS BESTDENT</b>	
<b>REFERENCE</b>	See attached annex	
<b>COMPANY</b>	CORIS ARMITAL SL PLAZA XAROL, NUM 26-28 POL. IND. LES GUIXERES 08915 BADALONA, SPAIN	
<b>CLASSIFICATION</b>	Medical Device, Class I, Directive 93/42/EEC	
<b>PRODUCT DESCRIPTION</b>	Instruments for dental practice.	
<b>SPECIFICATIONS</b>	Description of the material: Stainless Steel. Dimensions: As per drawing Finish: Smooth surface free of chash Rockwell hardness: Hardness max 40-44 Material type: AISI-410	
<b>PACKAGING</b>	Each instrument is packed in high-density polyethylene bag, sealed both ends.	
<b>SHELF LIFE</b>	N.A. The properties, function or use is not affected automatically, if properly stored.	
<b>INTENDED USE</b>	Intended to be used in the support function during the operations in the dental clinics by qualified personnel.	
<b>SAFETY INSTRUCTIONS</b>	The devices used in the analysis are re-useable, however cleaning and sterilizing is necessary before each use. If there is any indication of rust the instrument should not be used.	
<b>TRANSPORT AND STORAGE CONDITIONS</b>	Cleaning instructions are provided along with the instruments.	
<b>MSDS</b>	N.A.	
<b>INSTRUCTIONS FOR USE</b>	<ul style="list-style-type: none"> <li>- Sterilize before use.</li> <li>- Before sterilization remove existing packing, clean the instruments and pack in sterilize-able pouch/sheet.</li> <li>- Wear Gloves while using the instruments.</li> <li>- Be careful of the sharp point of the instruments, if any.</li> <li>- Be careful of the moving parts of the instruments.</li> <li>- The instruments must be stored in dry place and must be handled with care to prevent damage.</li> <li>- Only qualified person should use the healthcare devices. Use only for its intended purpose to ensure maximum effectiveness.</li> <li>- After use the instruments should be disposed off according to local laws.</li> </ul>	


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<b>CLEANING INSTRUCTIONS</b>	<p><i>Inner portions of joints of the devices need particular attention during cleaning.</i></p> <p><b>1) MANUAL CLEANING:</b> Equipment: Latex Gloves, Chloroxylenol Detergent, non-metallic brush and running water.</p> <p><b>Method:</b></p> <ol style="list-style-type: none"> <li>1. Wear Latex Gloves.</li> <li>2. Rinse instruments in water having temperature 30 to 40°C.</li> <li>3. Using brush apply detergent solution to all surfaces ensuring that joints of the instruments are cleaned both in open and closed positions.</li> <li>4. Rinse under clean running water for 3 to 4 minutes with temperature 30 to 40°C. Ensure that running water passes through cannulations and that blind wholes are repeatedly filled and emptied.</li> </ol> <p><b>2) AUTOMATIC CLEANING:</b> Equipment: Latex Gloves, liquid detergent having pH 7.0 to 8.3 and Washer / disinfectant unit preferably ultrasonic cleaning unit fitted with heater.</p> <p><b>Method:</b></p> <ul style="list-style-type: none"> <li>- Wear Latex Gloves.</li> <li>- Load instruments in a way that hinges / joints are open and cannulations holes can drain in the basket / hanger of the washer/disinfectant unit.</li> <li>- Rinse instruments under running water having temperature 30-40°C.</li> <li>- Place basket / hanger containing instruments into unit.</li> <li>- Run standard washing cycle for 5 to 6 minutes at 70-75°C.</li> <li>- Rinse under hot water for 3 to 4 minutes.</li> <li>- When unloading check cannulations, holes etc. for complete removal of visible soil etc. If necessary repeat cycle or use manual cleaning.</li> <li>- Dry the instruments using lint free cloth or dry air chamber.</li> </ul> <p><b>Disinfection:</b> Disinfectant solution like Chloroxylenol may be used in accordance with label instructions.</p> <p><b>Sterilization:</b></p> <p><b>Gas Sterilization</b>  The instruments may be gas sterilized using Ethylene Oxide mixture. Follow sterilizer manufacturer's recommendations. In other respects all instruments are suitable for ETO gas sterilization. The usually ethylene oxide mixture is 12%EO-88% FREON at 52°C 105 minutes but the sterilizer manufacturer's recommendation must be followed.</p> <p>or</p> <p><b>Steam Sterilization</b>  Instruments may be steam autoclaved at 121°C for 15 minutes or 134°C for 3.5 minutes.</p>
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