

BIEN AIR SURGERY – FRESAS Y CUCHILLAS PARA NEUROCIRUGIA

REFERENCIA	DESCRIPCION
547847	FRESA PM2 80K DIAMANTADA 3.1 X 125 mm
547870	FRESA PM2 80K DIAMANTADA 4.0 X 125mm
547871	FRESA PM2 80K DIAMANTE GRUESO 3.1 x 125mm
547872	FRESA PM2 80K DIAMANTE GRUESO 4.0 x 125mm
547873	FRESA PM2 80K DIAMANTE GRUESO 5.0 x 125mm

  		FICHA TÉCNICA DISPOSITIVOS MÉDICOS		
				
INDICACIONES: REALIZAR PROCESOS DE FRESADO Y SHAVER EN CIRUGIAS DE DIFERENTE TIPO PARA APLICACIONES EN OTORRINO, NEUROLOGIA, CIRUGIA PLASTICA, MAXILO FACIAL, RECONSTRUCCION DE CARA, CABEZA Y CUELLO, PEQUEÑAS CIRUGIAS DE MANO, PIE, COLUMNA, ETC.				
INFORMACIÓN GENERAL				
NOMBRE	SISTEMA DE FRESAMIENTO Y/O SHAVER PARA APLICACIONES EN MICROCIRUGIA-BIEN-AIR SURGERY SA			
NOMBRE GENÉRICO	SISTEMA DE FRESAMIENTO Y SHAVER			
MARCA	BIEN-AIR SURGERY SA.			
PERMISO DE COMERCIALIZACIÓN	INVIMA EBC-0020415			
COMPONENTES	EL PRESENTE REGISTRO AMPARA LOS MODELOS: OSSEOPRO, OSSEODUO, MODELOS DE PIEZA DE MANO: RECTA, CURVA, FISCH PM MICRO, PIEZA DE MANO RECTA Y CURVA INTRANASAL, PIEZA RECTA Y CONTRA ANGULO, PIEZA DE MANO OSSEOSTAP, OSSEOUNO Y OSSEOSTAP ADICIÓN DE REFERENCIA, Y TODAS SUS FRESAS MICROMOTOR RÁPIDO, ACCESORIOS Y REPUESTOS EXCLUSIVOS DEL EQUIPO			
TIPO DE DISPOSITIVO	EQUIPO BIOMEDICO TERAPEUTICO			
CLASIFICACION DE RIESGO	I	IIA	IIIB	
			X	
PAIS DE PROCEDENCIA	PRESENTACIÓN COMERCIAL			
SUIZA	UNIDAD			
				
REFERENCIAS Y TAMAÑOS DISPONIBLES PARA NEUROLOGIA				
				
REFERENCIAS Y TAMAÑOS DISPONIBLES EN FRESAS PARA 50K BURS				
VELOCIDAD MAXIMA DE USO 50'000 rpm PIEZA DE MANO DE 70 mm				
ACERO INOXIDABLE		Non sterile - 1 pce/box Sterile - 5 pcs/box		
		ø mm	Reusable	Single use
		0.6	1100290-001	1100416-005
		0.8	1100291-001	1100417-005
		1.0	1100292-001	1100418-005
		1.4	1100293-001	1100419-005
		1.8	1100294-001	1100420-005
		2.3	1100295-001	1100421-005
		2.7	1100296-001	1100422-005
		3.1	1100297-001	1100423-005
		3.5	1100298-001	1100424-005
		4.0	1100299-001	1100425-005
		4.5	1100300-001	1100426-005
		5.0	1100301-001	1100427-005
6.0	1100302-001	1100428-005		
7.0	1100303-001	1100429-005		

 Medinistros Equipos y dispositivos médicos  ISO 9001  CERTIFIED MANAGEMENT SYSTEM			FICHA TÉCNICA DISPOSITIVOS MÉDICOS  Bien Air <i>Surgery</i>																													
DIAMANTE		<table><tr><th>ø mm</th><th>Reusable</th></tr><tr><td>0.6</td><td>1100247-001</td></tr><tr><td>0.8</td><td>1100248-001</td></tr><tr><td>1.0</td><td>1100249-001</td></tr><tr><td>1.4</td><td>1100250-001</td></tr><tr><td>1.8</td><td>1100251-001</td></tr><tr><td>2.3</td><td>1100252-001</td></tr><tr><td>2.7</td><td>1100253-001</td></tr><tr><td>3.1</td><td>1100254-001</td></tr><tr><td>3.5</td><td>1100255-001</td></tr><tr><td>4.0</td><td>1100256-001</td></tr><tr><td>4.5</td><td>1100257-001</td></tr><tr><td>5.0</td><td>1100258-001</td></tr><tr><td>6.0</td><td>1100259-001</td></tr><tr><td>7.0</td><td>1100260-001</td></tr></table>	ø mm	Reusable	0.6	1100247-001	0.8	1100248-001	1.0	1100249-001	1.4	1100250-001	1.8	1100251-001	2.3	1100252-001	2.7	1100253-001	3.1	1100254-001	3.5	1100255-001	4.0	1100256-001	4.5	1100257-001	5.0	1100258-001	6.0	1100259-001	7.0	1100260-001
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CARBURO		<table><tr><th>ø mm</th><th>Reusable</th></tr><tr><td>0.5</td><td>1100261-001</td></tr><tr><td>0.8</td><td>1100262-001</td></tr><tr><td>1.0</td><td>1100263-001</td></tr><tr><td>1.4</td><td>1100264-001</td></tr><tr><td>1.8</td><td>1100265-001</td></tr><tr><td>2.3</td><td>1100266-001</td></tr><tr><td>2.7</td><td>1100267-001</td></tr><tr><td>3.1</td><td>1100268-001</td></tr><tr><td>3.5</td><td>1100269-001</td></tr><tr><td>4.0</td><td>1100270-001</td></tr><tr><td>4.5</td><td>1100271-001</td></tr><tr><td>5.0</td><td>1100272-001</td></tr><tr><td>6.0</td><td>1100273-001</td></tr><tr><td>7.0</td><td>1100274-001</td></tr></table>	ø mm	Reusable	0.5	1100261-001	0.8	1100262-001	1.0	1100263-001	1.4	1100264-001	1.8	1100265-001	2.3	1100266-001	2.7	1100267-001	3.1	1100268-001	3.5	1100269-001	4.0	1100270-001	4.5	1100271-001	5.0	1100272-001	6.0	1100273-001	7.0	1100274-001
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CORTE TRANSVERSAL		<table><tr><th>ø mm</th><th>Reusable</th></tr><tr><td>1.4</td><td>1100438-001</td></tr><tr><td>2.3</td><td>1100439-001</td></tr><tr><td>3.1</td><td>1100440-001</td></tr><tr><td>4.0</td><td>1100441-001</td></tr><tr><td>5.0</td><td>1100442-001</td></tr><tr><td>6.0</td><td>1100443-001</td></tr></table>	ø mm	Reusable	1.4	1100438-001	2.3	1100439-001	3.1	1100440-001	4.0	1100441-001	5.0	1100442-001	6.0	1100443-001																
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CÓNICO CARBURO		<table><tr><th>ø mm</th><th>Reusable</th><th>Single use</th></tr><tr><td>6.0</td><td>1100275-001</td><td>1100430-001</td></tr><tr><td>7.0</td><td>1100276-001</td><td>1100431-001</td></tr></table>	ø mm	Reusable	Single use	6.0	1100275-001	1100430-001	7.0	1100276-001	1100431-001																					
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REFERENCIAS Y TAMAÑOS DISPONIBLES EN FRESAS PARA 50K BURS			
VELOCIDAD MAXIMA DE USO 50'000 rpm PIEZA DE MANO DE 80 mm			
DIAMANTAD A		ø mm	Reusable
		0.6	1100389-001
		0.8	1100390-001
		1.0	1100391-001
		1.4	1100469-001
		1.8	1100470-001
		2.3	1100471-001
REFERENCIAS Y TAMAÑOS DISPONIBLES EN FRESAS PARA 80K BURS			
VELOCIDAD MAXIMA DE USO 80'000 rpm PIEZA DE MANO DE 70 mm			
ACERO INOXIDABLE		ø mm	Single use
		0.6	1100351-005
		0.8	1100352-005
		1.0	1100353-005
		1.4	1100354-005
		1.8	1100355-005
		2.3	1100356-005
		2.7	1100357-005
		3.1	1100358-005
		3.5	1100359-005
		4.0	1100360-005
		4.5	1100361-005
		5.0	1100362-005
		6.0	1100363-005
		7.0	1100364-005
DIAMANTE		ø mm	Single use
		0.6	1100365-001
		0.8	1100366-001
		1.0	1100367-001
		1.4	1100368-001
		1.8	1100369-001
		2.3	1100370-001
		2.7	1100371-001
		3.1	1100372-001
		3.5	1100373-001
		4.0	1100374-001
		4.5	1100375-001
		5.0	1100376-001
		6.0	1100377-001
		7.0	1100378-001
CARBIDE		ø mm	Single use
		0.5	1100392-001
		0.8	1100393-001
		1.0	1100394-001
		1.4	1100395-001
		1.8	1100396-001
		2.3	1100397-001
		2.7	1100398-001
		3.1	1100399-001
		3.5	1100400-001
		4.0	1100401-001
		4.5	1100402-001
		5.0	1100403-001
		6.0	1100404-001
		7.0	1100405-001

 Medinistros Equipos y dispositivos médicos  icontec ISO 9001  CERTIFICADO IQNet MANAGEMENT SYSTEM <tr><th colspan="3">FICHA TÉCNICA DISPOSITIVOS MÉDICOS</th></tr> <tr><th colspan="3">  Bien Air Surgery </th></tr> <tr><td>COMPLETO DE CARBURO</td><td></td><td><table><tr><th>ø mm</th><th>Single use</th></tr><tr><td>0.5</td><td>1100475-001</td></tr><tr><td>1.0</td><td>1100462-001</td></tr><tr><td>1.5</td><td>1100463-001</td></tr><tr><td>2.0</td><td>1100464-001</td></tr><tr><td>2.3</td><td>1100465-001</td></tr><tr><td>3.0</td><td>1100466-001</td></tr><tr><td>3.5</td><td>1100483-001</td></tr><tr><td>4.0</td><td>1100467-001</td></tr><tr><td>4.5</td><td>1100484-001</td></tr><tr><td>5.0</td><td>1100476-001</td></tr><tr><td>6.0</td><td>1100468-001</td></tr><tr><td>7.0</td><td>1100477-001</td></tr></table></td></tr> <tr><td>GRUESO DE DIAMANTE</td><td></td><td><table><tr><th>ø mm</th><th>Single use</th></tr><tr><td>2.3</td><td>1100379-001</td></tr><tr><td>3.1</td><td>1100380-001</td></tr></table></td></tr> <tr><td>DIAMANTE EXTRA GRUESO</td><td></td><td><table><tr><th>ø mm</th><th>Single use</th></tr><tr><td>4.5</td><td>1100381-001</td></tr><tr><td>6.0</td><td>1100382-001</td></tr></table></td></tr> <tr><td>FÓSFORO</td><td></td><td><table><tr><th>ø mm</th><th>Single use</th></tr><tr><td>1.8</td><td>1100460-001</td></tr><tr><td>3.0</td><td>1100461-001</td></tr></table></td></tr> <tr><td>TALADRADO INOX</td><td></td><td><table><tr><th>ø x L mm</th><th>Single use</th></tr><tr><td>1.5 x 12</td><td>1100459-001</td></tr><tr><td>1.1 x 5</td><td>1100473-001</td></tr></table></td></tr> <tr><td>CRANEOTO MÍA RECTA</td><td></td><td><table><tr><th>L mm</th><th>Single use</th></tr><tr><td>10</td><td>1100383-001</td></tr><tr><td>15</td><td>1100384-001</td></tr><tr><td>25</td><td>1100414-001</td></tr></table></td></tr>			FICHA TÉCNICA DISPOSITIVOS MÉDICOS			 Bien Air Surgery			COMPLETO DE CARBURO		<table><tr><th>ø mm</th><th>Single use</th></tr><tr><td>0.5</td><td>1100475-001</td></tr><tr><td>1.0</td><td>1100462-001</td></tr><tr><td>1.5</td><td>1100463-001</td></tr><tr><td>2.0</td><td>1100464-001</td></tr><tr><td>2.3</td><td>1100465-001</td></tr><tr><td>3.0</td><td>1100466-001</td></tr><tr><td>3.5</td><td>1100483-001</td></tr><tr><td>4.0</td><td>1100467-001</td></tr><tr><td>4.5</td><td>1100484-001</td></tr><tr><td>5.0</td><td>1100476-001</td></tr><tr><td>6.0</td><td>1100468-001</td></tr><tr><td>7.0</td><td>1100477-001</td></tr></table>	ø mm	Single use	0.5	1100475-001	1.0	1100462-001	1.5	1100463-001	2.0	1100464-001	2.3	1100465-001	3.0	1100466-001	3.5	1100483-001	4.0	1100467-001	4.5	1100484-001	5.0	1100476-001	6.0	1100468-001	7.0	1100477-001	GRUESO DE DIAMANTE		<table><tr><th>ø mm</th><th>Single use</th></tr><tr><td>2.3</td><td>1100379-001</td></tr><tr><td>3.1</td><td>1100380-001</td></tr></table>	ø mm	Single use	2.3	1100379-001	3.1	1100380-001	DIAMANTE EXTRA GRUESO		<table><tr><th>ø mm</th><th>Single use</th></tr><tr><td>4.5</td><td>1100381-001</td></tr><tr><td>6.0</td><td>1100382-001</td></tr></table>	ø mm	Single use	4.5	1100381-001	6.0	1100382-001	FÓSFORO		<table><tr><th>ø mm</th><th>Single use</th></tr><tr><td>1.8</td><td>1100460-001</td></tr><tr><td>3.0</td><td>1100461-001</td></tr></table>	ø mm	Single use	1.8	1100460-001	3.0	1100461-001	TALADRADO INOX		<table><tr><th>ø x L mm</th><th>Single use</th></tr><tr><td>1.5 x 12</td><td>1100459-001</td></tr><tr><td>1.1 x 5</td><td>1100473-001</td></tr></table>	ø x L mm	Single use	1.5 x 12	1100459-001	1.1 x 5	1100473-001	CRANEOTO MÍA RECTA		<table><tr><th>L mm</th><th>Single use</th></tr><tr><td>10</td><td>1100383-001</td></tr><tr><td>15</td><td>1100384-001</td></tr><tr><td>25</td><td>1100414-001</td></tr></table>	L mm	Single use	10	1100383-001	15	1100384-001	25	1100414-001
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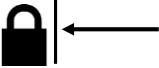
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	FICHA TÉCNICA DISPOSITIVOS MÉDICOS

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  	FICHA TÉCNICA DISPOSITIVOS MÉDICOS 
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CONTRAINDICACIONES			
Ninguna conocida hasta la actualidad.			
PRECAUCIONES - ADVERTENCIAS			
Las especificaciones técnica y cotas incluidas en las presentes instrucciones se facilitan únicamente a título indicativo. Estas no podrán dar lugar a ningún tipo de reclamación. El fabricante se reserva el derecho de añadir mejoras técnicas en sus equipamientos sin modificar las presentes instrucciones. - El dispositivo se emplea únicamente cuando se encuentre en buenas condiciones físicas y funcionales. - Cualquier detección de vibración excesiva o recalentamiento del dispositivo debe interrumpirse inmediatamente el trabajo y acudir a un centro de reparación autorizado por Bien Air Surgery.			
CONDICIONES AMBIENTALES			
Trabajo	Temperatura: Humedad relativa: Presión atmosférica:	+10°C a +30°C 20% a 80% condensación incluida de 700 hPa a 1060 hPa	
Transporte	Temperatura: Humedad relativa: Presión atmosférica:	- 25°C a + 70°C 10% a 100% condensación incluida de 500 hPa a 1060 hPa	
Almacén	Temperatura: Humedad relativa: Presión atmosférica:	+10°C a +30°C 20% a 80% condensación incluida de 500 hPa a 1060 hPa	
CONDICIONES AMBIENTALES			
 0120	Marca de conformidad CE con número del organismo acreditado	RX Only	Limitación de venta de este dispositivo por orden de un medico autorizado
	ATENCIÓN ! Consulte los documentos adjuntos		Esterilizable en autoclave hasta la temperatura indicada
	Admite lavado a máquina		Fabricante
	Pieza de mano cerrada		Dirección de apertura de la pieza de mano



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