

BIEN AIR SURGERY – FRESAS Y CUCHILLAS PARA NEUROCIRUGIA

REFERENCIA	DESCRIPCION
547879	FRESA PM2 80K DIAMANTADA 3.1 x 150 mm
547880	FRESA PM2 80K DIAMANTADA 4.0 x 150 mm
1100340	FRESA PM2 80K MATCHSTICK ACERO 1.8x125 mm
1100341	FRESA PM2 80K MATCHSTICK ACERO 3.0 x 125 mm
547877	FRESA PM2 80K ACERO 3.1x150mm

  		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
ø mm	Reusable																															
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0.8	1100248-001																															
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7.0	1100260-001																															
DIAMANTE DE GRANO GRUESO		<table><tr><th>ø mm</th><th>Reusable</th></tr><tr><td>2.3</td><td>1100304-001</td></tr><tr><td>2.7</td><td>1100305-001</td></tr><tr><td>3.1</td><td>1100306-001</td></tr><tr><td>3.5</td><td>1100307-001</td></tr><tr><td>4.0</td><td>1100433-001</td></tr><tr><td>4.5</td><td>1100434-001</td></tr><tr><td>5.0</td><td>1100435-001</td></tr><tr><td>6.0</td><td>1100436-001</td></tr><tr><td>7.0</td><td>1100437-001</td></tr></table>	ø mm	Reusable	2.3	1100304-001	2.7	1100305-001	3.1	1100306-001	3.5	1100307-001	4.0	1100433-001	4.5	1100434-001	5.0	1100435-001	6.0	1100436-001	7.0	1100437-001										
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VELOCIDAD MAXIMA DE USO 50'000 rpm PIEZA DE MANO DE 70 mm																																
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
ø mm	Reusable																															
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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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6.0	1100443-001																															
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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6.0	1100275-001	1100430-001																														
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 Medinistros Equipos y dispositivos médicos  ISO 9001  CERTIFICADO MANAGEMENT SYSTEM		FICHA TÉCNICA DISPOSITIVOS MÉDICOS 	
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 00-2030201  CERTIFICADO IQNet MANAGEMENT SYSTEM 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
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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																				
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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																				
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ø mm	Single use																											
1.8	1100460-001																											
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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																				
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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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 Medinistros Equipos y dispositivos médicos			FICHA TÉCNICA DISPOSITIVOS MÉDICOS 
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CRANEOTOMÍA ESPIRAL		<table><tr><th>L mm</th><th>Single use</th></tr><tr><td>10</td><td>1100386-001</td></tr><tr><td>15</td><td>1100387-001</td></tr><tr><td>25</td><td>1100413-001</td></tr></table>	L mm	Single use	10	1100386-001	15	1100387-001	25	1100413-001								
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REFERENCIAS Y TAMAÑOS DISPONIBLES EN FRESAS PARA 80K BURS																		
VELOCIDAD MÁXIMA DE USO 80'000 rpm PIEZA DE MANO DE 95 mm																		
DRUM		<table><tr><th>ø x L mm</th><th>Single use</th></tr><tr><td>5 x 10</td><td>stainless steel: 1100339-001</td></tr><tr><td>4 x 8</td><td>coarse diamond: 1100338-001</td></tr></table>	ø x L mm	Single use	5 x 10	stainless steel: 1100339-001	4 x 8	coarse diamond: 1100338-001										
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ACERO INOXIDABLE		<table><tr><th>ø mm</th><th>Single use</th></tr><tr><td>1.0</td><td>1100446-001</td></tr><tr><td>1.8</td><td>1100447-001</td></tr><tr><td>2.3</td><td>1100448-001</td></tr><tr><td>3.1</td><td>1100449-001</td></tr><tr><td>4.0</td><td>1100450-001</td></tr><tr><td>5.0</td><td>1100451-001</td></tr><tr><td>6.0</td><td>1100452-001</td></tr></table>	ø mm	Single use	1.0	1100446-001	1.8	1100447-001	2.3	1100448-001	3.1	1100449-001	4.0	1100450-001	5.0	1100451-001	6.0	1100452-001
ø mm	Single use																	
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DIAMANTADA		<table><tr><th>ø mm</th><th>Single use</th></tr><tr><td>1.0</td><td>1100320-001</td></tr><tr><td>1.8</td><td>1100321-001</td></tr><tr><td>2.3</td><td>1100322-001</td></tr><tr><td>3.1</td><td>1100323-001</td></tr><tr><td>4.0</td><td>1100324-001</td></tr></table>	ø mm	Single use	1.0	1100320-001	1.8	1100321-001	2.3	1100322-001	3.1	1100323-001	4.0	1100324-001				
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DIAMANTE GRUESO		<table><tr><th>ø mm</th><th>Single use</th></tr><tr><td>3.1</td><td>1100325-001</td></tr><tr><td>4.0</td><td>1100326-001</td></tr><tr><td>5.0</td><td>1100327-001</td></tr><tr><td>6.0</td><td>1100328-001</td></tr></table>	ø mm	Single use	3.1	1100325-001	4.0	1100326-001	5.0	1100327-001	6.0	1100328-001						
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DIAMANTE EXTRA GRUESO		<table><tr><th>ø mm</th><th>Single use</th></tr><tr><td>3.8</td><td>1100444-001</td></tr><tr><td>4.7</td><td>1100445-001</td></tr></table>	ø mm	Single use	3.8	1100444-001	4.7	1100445-001										
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REFERENCIAS Y TAMAÑOS DISPONIBLES EN FRESAS PARA 80K BURS																	
VELOCIDAD MAXIMA DE USO 80'000 rpm PIEZA DE MANO DE 125 mm																	
ACERO INOXIDABLE		<table><tr><th>ø mm</th><th>Single use</th></tr><tr><td>1.8</td><td>1100453-001</td></tr><tr><td>2.3</td><td>1100454-001</td></tr><tr><td>3.1</td><td>1100455-001</td></tr><tr><td>4.0</td><td>1100456-001</td></tr><tr><td>5.0</td><td>1100457-001</td></tr><tr><td>6.0</td><td>1100458-001</td></tr></table>		ø mm	Single use	1.8	1100453-001	2.3	1100454-001	3.1	1100455-001	4.0	1100456-001	5.0	1100457-001	6.0	1100458-001
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DIAMANTAD A		<table><tr><th>ø mm</th><th>Single use</th></tr><tr><td>1.0</td><td>1100308-001</td></tr><tr><td>1.8</td><td>1100309-001</td></tr><tr><td>2.3</td><td>1100310-001</td></tr><tr><td>3.1</td><td>1100311-001</td></tr><tr><td>4.0</td><td>1100312-001</td></tr></table>		ø mm	Single use	1.0	1100308-001	1.8	1100309-001	2.3	1100310-001	3.1	1100311-001	4.0	1100312-001		
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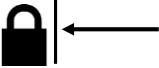
	FICHA TÉCNICA DISPOSITIVOS MÉDICOS

DIAMANTADA		<table><tr><td>ø mm</td><td>Single use</td></tr><tr><td>1.0</td><td>1100329-001</td></tr><tr><td>1.8</td><td>1100330-001</td></tr><tr><td>3.1</td><td>1100331-001</td></tr><tr><td>4.0</td><td>1100332-001</td></tr></table>	ø mm	Single use	1.0	1100329-001	1.8	1100330-001	3.1	1100331-001	4.0	1100332-001
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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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