

BIEN AIR SURGERY – FRESAS Y CUCHILLAS PARA NEUROCIRUGIA

REFERENCIA	DESCRIPCION
1100405	FRESA PM2 80K CARBURO 7.0x70 mm
1100413	FRESA CRANIOTOMO ESPIRAL 25MM
1100414	FRESA CRANIOTOMO RECTA 25mm
1100468	FRESA PM2 80K EXTRACARBURO 6.0x70 mm
547845	FRESA PM2 80K DIAMANTADA 2.3 X 125 mm

  		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  icontec ISO 9001 ISO-9001:2015  CERTIFIED IQNet MANAGEMENT SYSTEM			FICHA TÉCNICA DISPOSITIVOS MÉDICOS																															
																																		
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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		2.3	1100252-001																															
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		3.5	1100255-001																															
		4.0	1100256-001																															
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5.0	1100258-001																																	
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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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		REFERENCIAS Y TAMAÑOS DISPONIBLES EN FRESAS PARA 50K BURS																																
		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																															
		0.5	1100261-001																															
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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																
		ø mm	Reusable																															
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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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		6.0	1100275-001	1100430-001																														
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 Medinistros Equipos y dispositivos médicos  icontec ISO 9001 ISO-2103201  IQNet CERTIFIED MANAGEMENT SYSTEM		FICHA TÉCNICA DISPOSITIVOS MÉDICOS  Bien Air <i>Surgery</i>	
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 10-20202020  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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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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 Medinistros Equipos y dispositivos médicos			FICHA TÉCNICA DISPOSITIVOS MÉDICOS 
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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
ø mm	Single use															
1.8	1100453-001															
2.3	1100454-001															
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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		
ø mm	Single use															
1.0	1100308-001															
1.8	1100309-001															
2.3	1100310-001															
3.1	1100311-001															
4.0	1100312-001															
DIAMANTE GRUESO		<table><tr><th>ø mm</th><th>Single use</th></tr><tr><td>3.1</td><td>1100313-001</td></tr><tr><td>4.0</td><td>1100314-001</td></tr><tr><td>5.0</td><td>1100315-001</td></tr></table>	ø mm	Single use	3.1	1100313-001	4.0	1100314-001	5.0	1100315-001						
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DIAMANTE EXTRA GUESO		<table><tr><th>ø mm</th><th>Single use</th></tr><tr><td>3.8</td><td>1100316-001</td></tr><tr><td>4.7</td><td>1100317-001</td></tr></table>	ø mm	Single use	3.8	1100316-001	4.7	1100317-001								
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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>3.1</td><td>1100344-001</td></tr><tr><td>4.0</td><td>1100345-001</td></tr></table>	ø mm	Single use	3.1	1100344-001	4.0	1100345-001								
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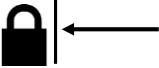
	FICHA TÉCNICA DISPOSITIVOS MÉDICOS

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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DRUM		<table><tr><td>ø x L mm</td><td>Single use</td></tr><tr><td>5 x 10</td><td>stainless steel: 1100343-001</td></tr><tr><td>4 x 8</td><td>coarse diamond: 1100342-001</td></tr></table>	ø x L mm	Single use	5 x 10	stainless steel: 1100343-001	4 x 8	coarse diamond: 1100342-001				
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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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