

BIEN AIR SURGERY – FRESAS Y CUCHILLAS PARA NEUROCIRUGIA

REFERENCIA	DESCRIPCION
1100387	FRESA CRANIOTOMO ESPIRAL 15mm
1100399	FRESA PM2 80K CARBURO 3.1x70 mm
1100401	FRESA PM2 80K CARBURO 4.0x70 mm
1100403	FRESA PM2 80K CARBURO 5.0x70 mm
1100404	FRESA PM2 80K CARBURO 6.0x70 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																																															
																																																
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VELOCIDAD MAXIMA DE USO 50'000 rpm PIEZA DE MANO DE 70 mm																																																
ACERO INOXIDABLE		Non sterile - 1 pce/box Sterile - 5 pcs/box																																														
		<table border="1"> <thead> <tr> <th>ø mm</th> <th>Reusable</th> <th>Single use</th> </tr> </thead> <tbody> <tr><td>0.6</td><td>1100290-001</td><td>1100416-005</td></tr> <tr><td>0.8</td><td>1100291-001</td><td>1100417-005</td></tr> <tr><td>1.0</td><td>1100292-001</td><td>1100418-005</td></tr> <tr><td>1.4</td><td>1100293-001</td><td>1100419-005</td></tr> <tr><td>1.8</td><td>1100294-001</td><td>1100420-005</td></tr> <tr><td>2.3</td><td>1100295-001</td><td>1100421-005</td></tr> <tr><td>2.7</td><td>1100296-001</td><td>1100422-005</td></tr> <tr><td>3.1</td><td>1100297-001</td><td>1100423-005</td></tr> <tr><td>3.5</td><td>1100298-001</td><td>1100424-005</td></tr> <tr><td>4.0</td><td>1100299-001</td><td>1100425-005</td></tr> <tr><td>4.5</td><td>1100300-001</td><td>1100426-005</td></tr> <tr><td>5.0</td><td>1100301-001</td><td>1100427-005</td></tr> <tr><td>6.0</td><td>1100302-001</td><td>1100428-005</td></tr> <tr><td>7.0</td><td>1100303-001</td><td>1100429-005</td></tr> </tbody> </table>	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	
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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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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

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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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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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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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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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4.7	1100445-001																	

REFERENCIAS Y TAMAÑOS DISPONIBLES EN FRESAS PARA 80K BURS

VELOCIDAD MÁXIMA 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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4.0	1100456-001															
5.0	1100457-001															
6.0	1100458-001															
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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2.3	1100310-001															
3.1	1100311-001															
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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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4.7	1100317-001															

REFERENCIAS Y TAMAÑOS DISPONIBLES EN FRESAS PARA 80K BURS

VELOCIDAD MÁXIMA DE USO 80'000 rpm PIEZA DE MANO DE 125 mm

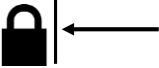
ACERO INOXIDABLE			
		ø mm	Single use
		3.1	1100344-001
		4.0	1100345-001

	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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4.0	1100334-001											
5.0	1100335-001											
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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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VELOCIDAD MAXIMA DE USO 80'000 rpm PIEZA DE MANO DE 150 mm												
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3.1	1100333-001											
4.0	1100334-001											
5.0	1100335-001											

FICHA TÉCNICA DISPOSITIVOS MÉDICOS															
REFERENCIAS Y TAMAÑOS DISPONIBLES EN FRESAS PARA 80K BURS															
VELOCIDAD MÁXIMA DE USO 80'000 rpm PIEZA DE MANO DE 150 mm															
FÓSFORO	 <table border="1"> <thead> <tr> <th>ø mm</th><th>Single use</th></tr> </thead> <tbody> <tr> <td>1.8</td><td>1100481-001</td></tr> <tr> <td>3.0</td><td>1100482-001</td></tr> </tbody> </table>	ø mm	Single use	1.8	1100481-001	3.0	1100482-001								
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3.0	1100482-001														
LÍNEA DE IRRIGACIÓN	 <table border="1"> <thead> <tr> <th colspan="2">LINEAS DE IRRIGACIÓN</th></tr> </thead> <tbody> <tr> <td>REF</td><td>1100037-010</td></tr> <tr> <td colspan="2">ESTERIL - UN SOLO USO</td></tr> <tr> <td>CAUDAL</td><td>30 / 130 mL/min</td></tr> <tr> <td colspan="2">MANGUERA DE SILICONA BLANCA</td></tr> <tr> <td>CAUDAL</td><td>15 / 65 mL/min</td></tr> <tr> <td colspan="2">MANGUERA DE SILICONA VERDE</td></tr> </tbody> </table>	LINEAS DE IRRIGACIÓN		REF	1100037-010	ESTERIL - UN SOLO USO		CAUDAL	30 / 130 mL/min	MANGUERA DE SILICONA BLANCA		CAUDAL	15 / 65 mL/min	MANGUERA DE SILICONA VERDE	
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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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